US010426646B2

(12) **United States Patent**
Roeder et al.

(10) **Patent No.: US 10,426,646 B2**
(45) **Date of Patent: Oct. 1, 2019**

(54) **PRE-LOADED DELIVERY DEVICE WITH TRI-FOLD PROXIMAL PROSTHESIS ATTACHMENT**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 547 days.

(21) Appl. No.: **15/041,433**

(22) Filed: **Feb. 11, 2016**

(65) **Prior Publication Data**

US 2016/0256301 A1 Sep. 8, 2016

Related U.S. Application Data

(60) Provisional application No. 62/128,705, filed on Mar. 5, 2015, provisional application No. 62/148,006, filed on Apr. 15, 2015.

(51) **Int. Cl.**
A61F 2/95 (2013.01)
A61F 2/966 (2013.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 2/966*** (2013.01); ***A61F 2/07*** (2013.01); *A61F 2002/061* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61F 2/07; A61F 2/844; A61F 2002/061; A61F 2002/9505; A61F 2002/9511;
(Continued)

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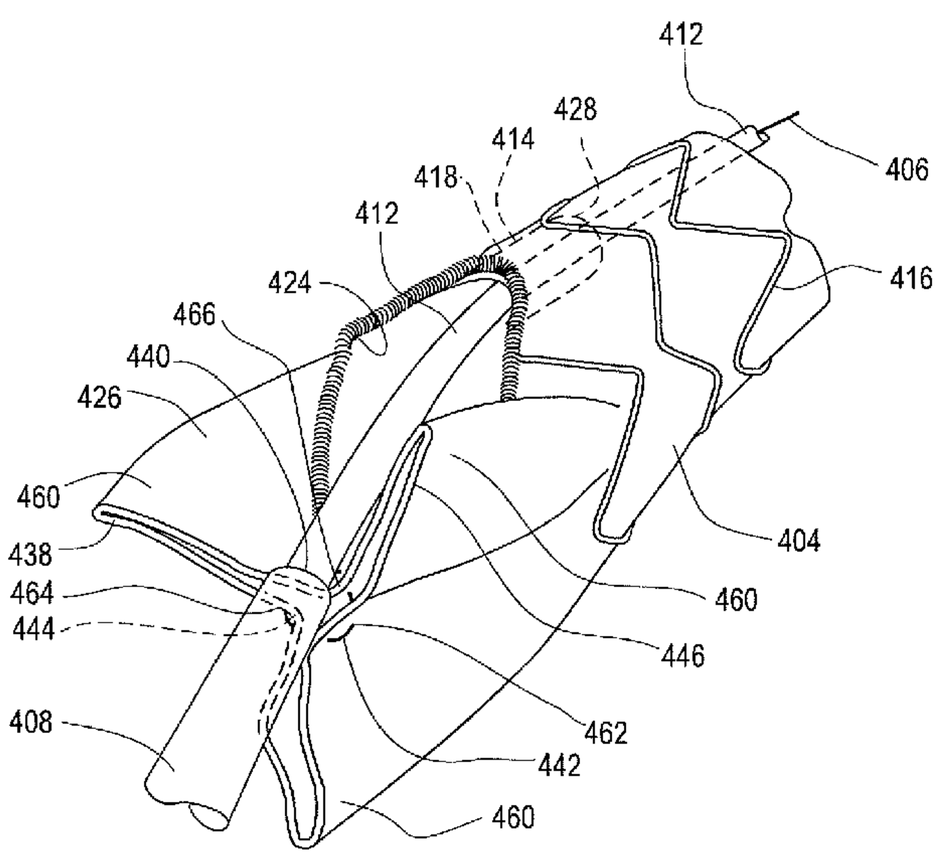
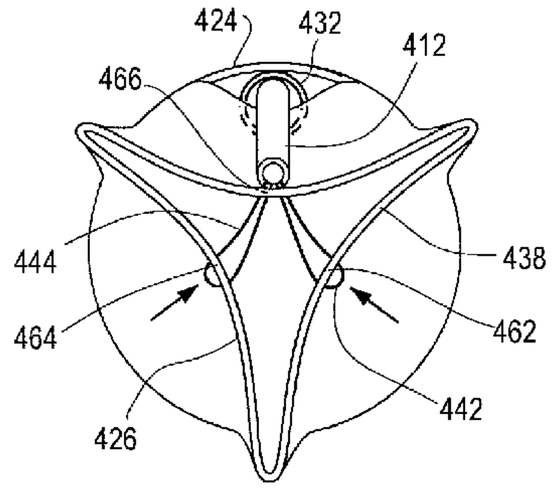
(57) **ABSTRACT**

A pre-loaded prosthesis delivery device is described. In one example, the prosthesis delivery device is pre-loaded with a single wire that allows the device to be tracked into place within a vessel and also facilitates cannulation of a branch vessel. The delivery device further comprises a prosthesis that is releasably coupled to a delivery catheter by using two attachment wires to secure the proximal end of the prosthesis to the delivery device in a tri-fold configuration.

20 Claims, 15 Drawing Sheets





(51) **Int. Cl.**
A61F 2/07 (2013.01)
A61F 2/06 (2013.01)

(52) **U.S. Cl.**
CPC *A61F 2002/9505* (2013.01); *A61F 2002/9511* (2013.01); *A61F 2230/005* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2002/9522; A61F 2/95; A61F 2/954; A61F 2/962; A61F 2/966
See application file for complete search history.

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Fig. 1

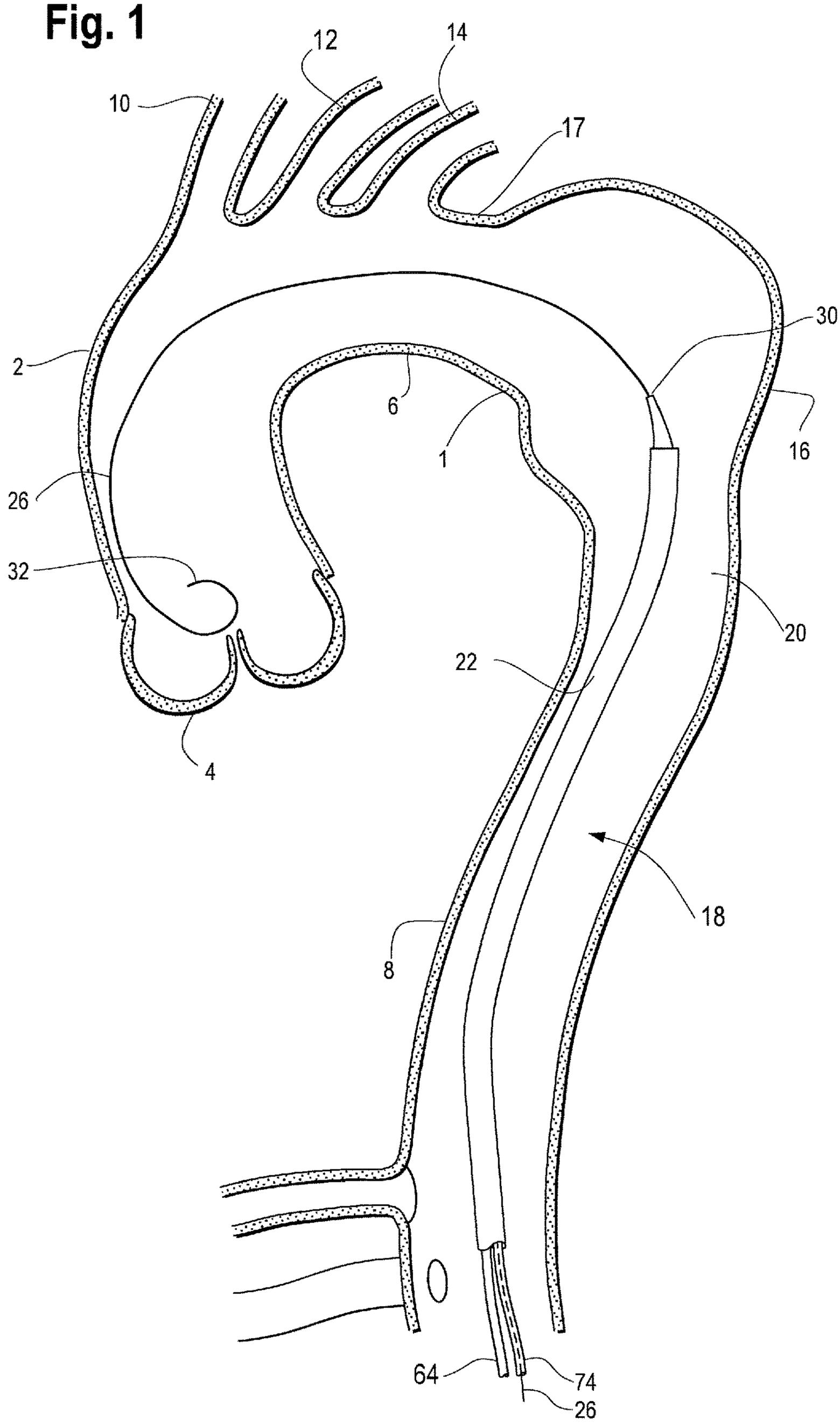

Fig. 2

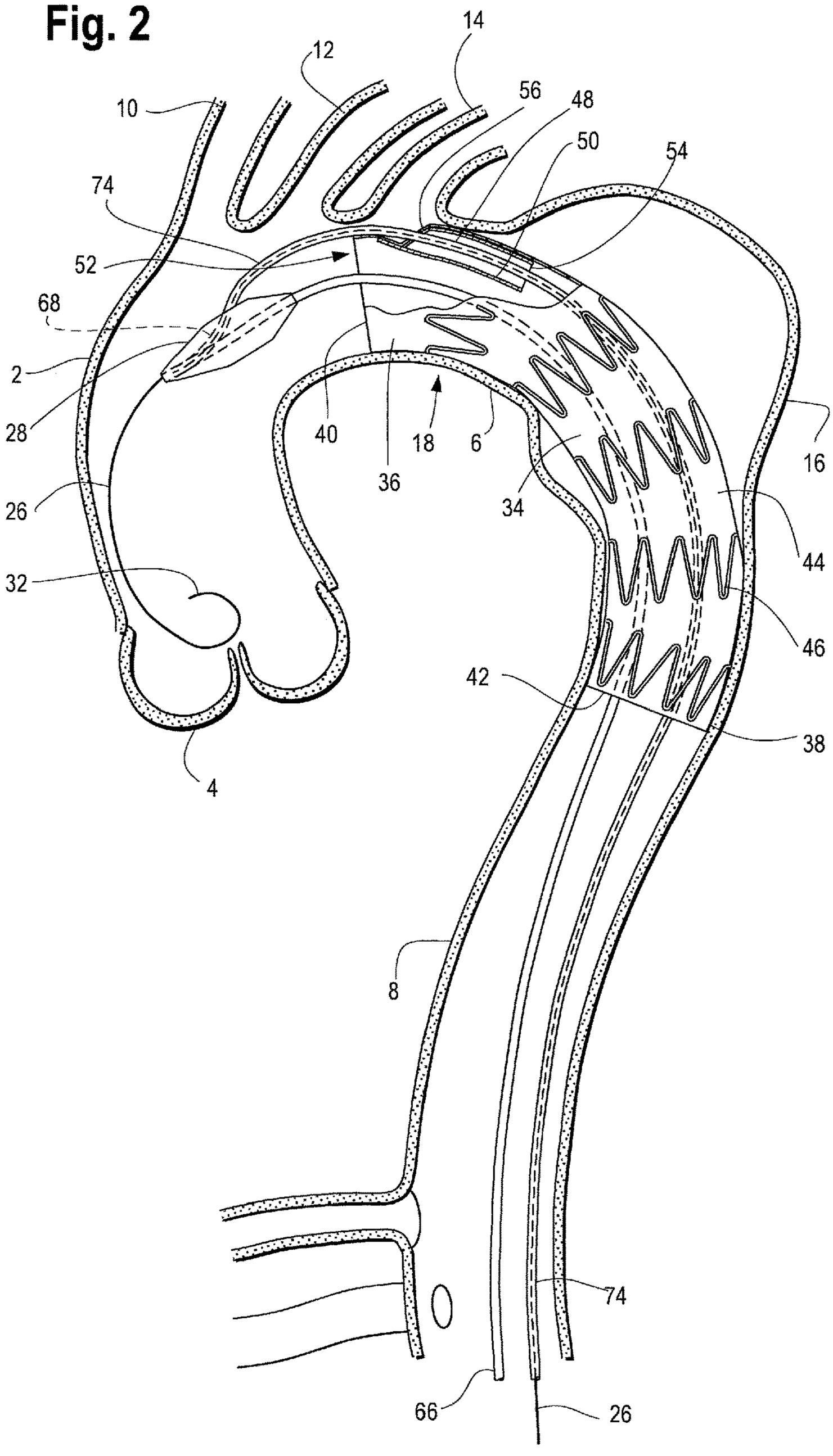
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Fig. 3

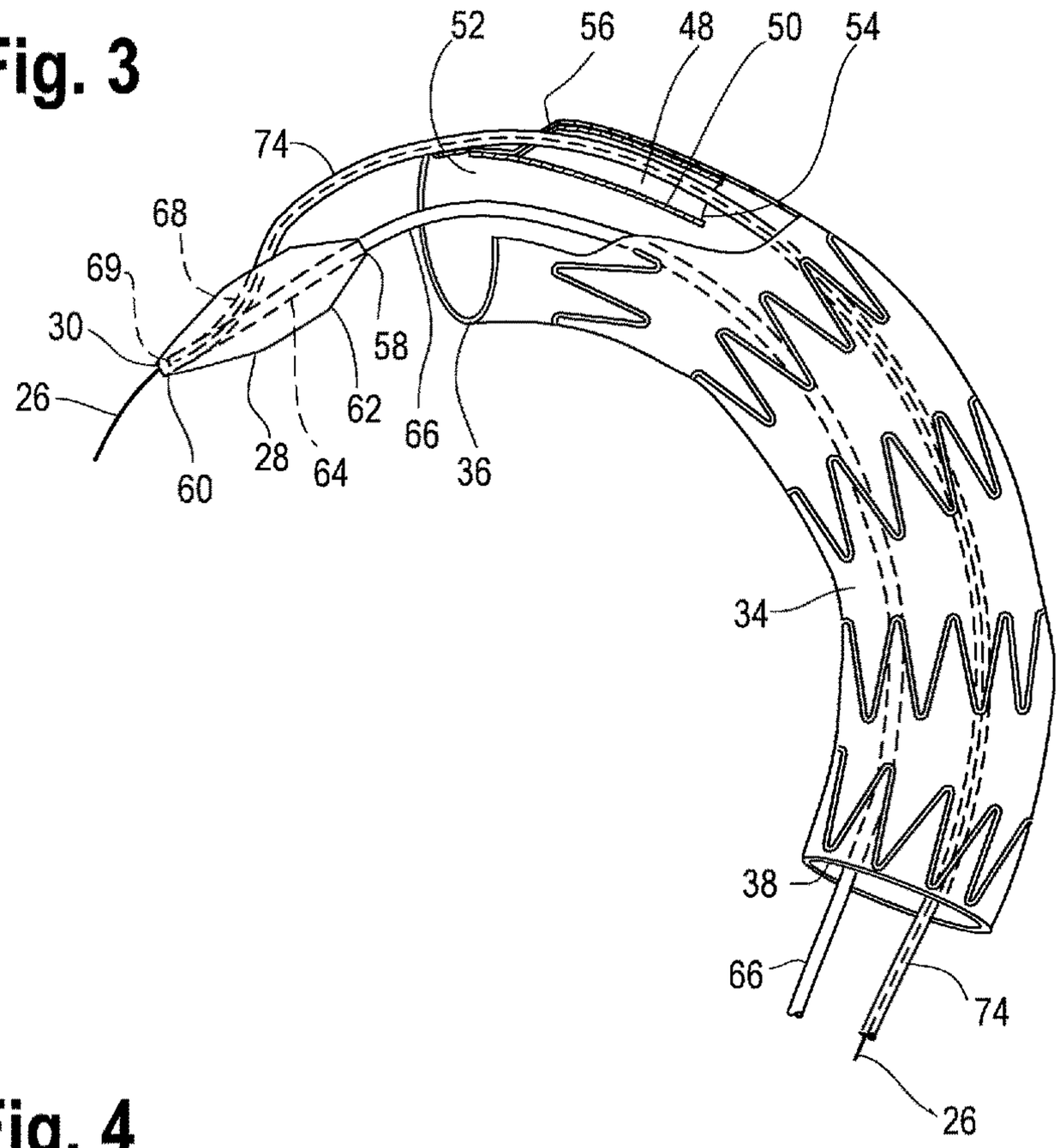
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Fig. 4

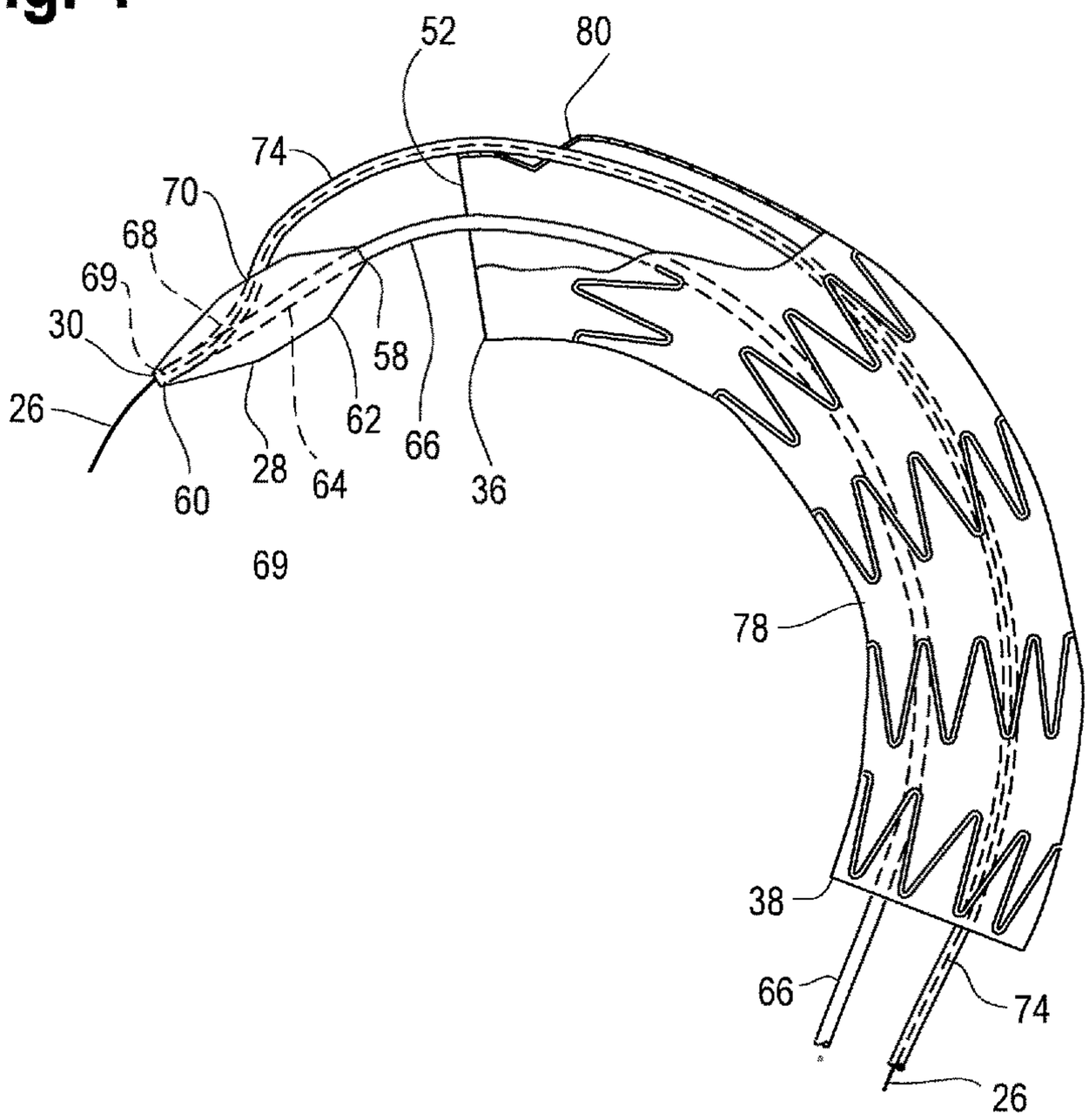
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Fig. 5

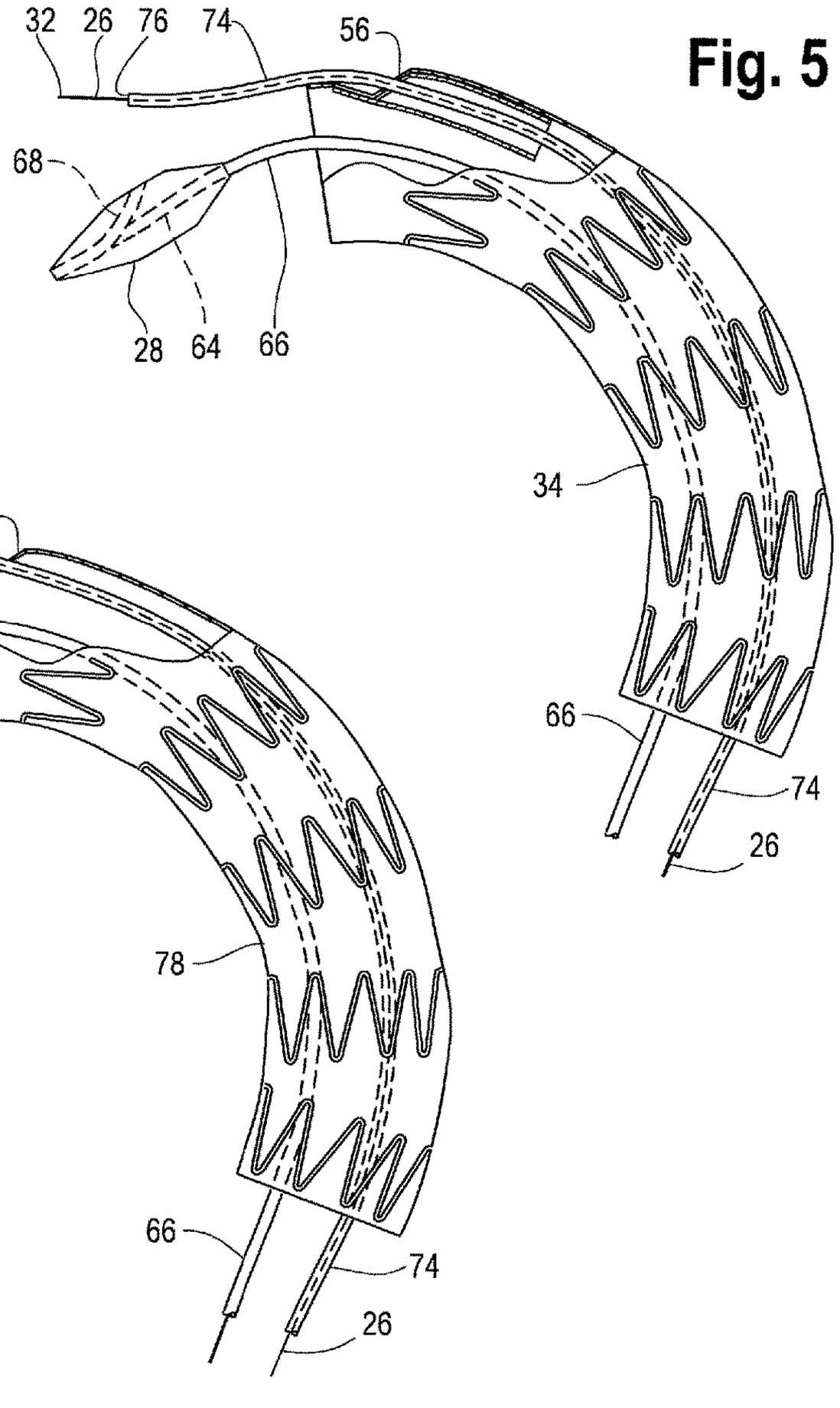
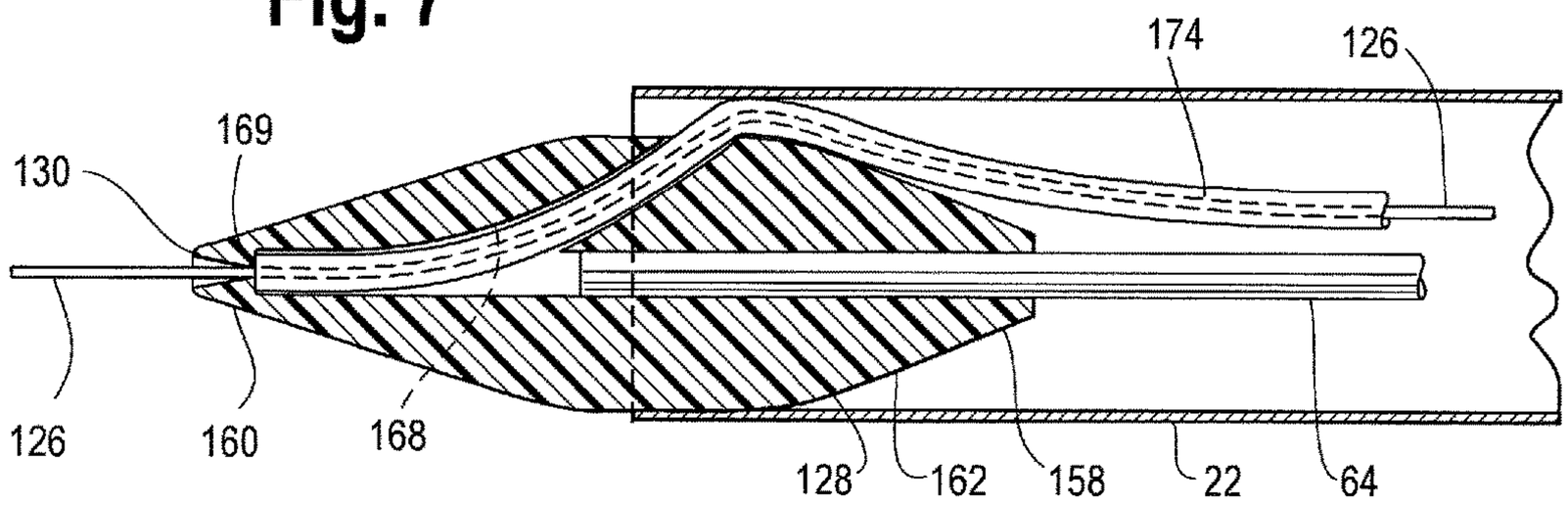


Fig. 6

Fig. 7



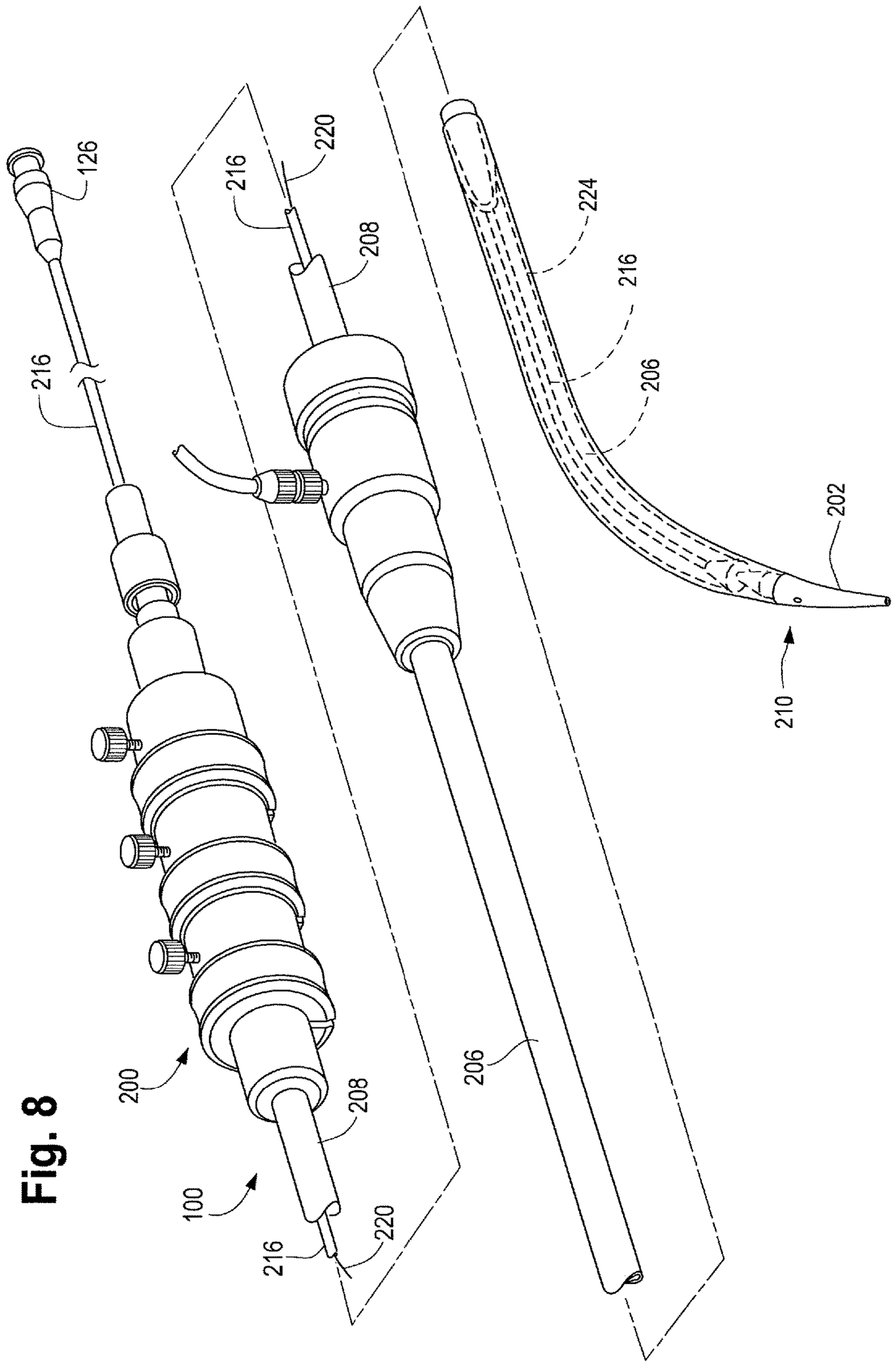
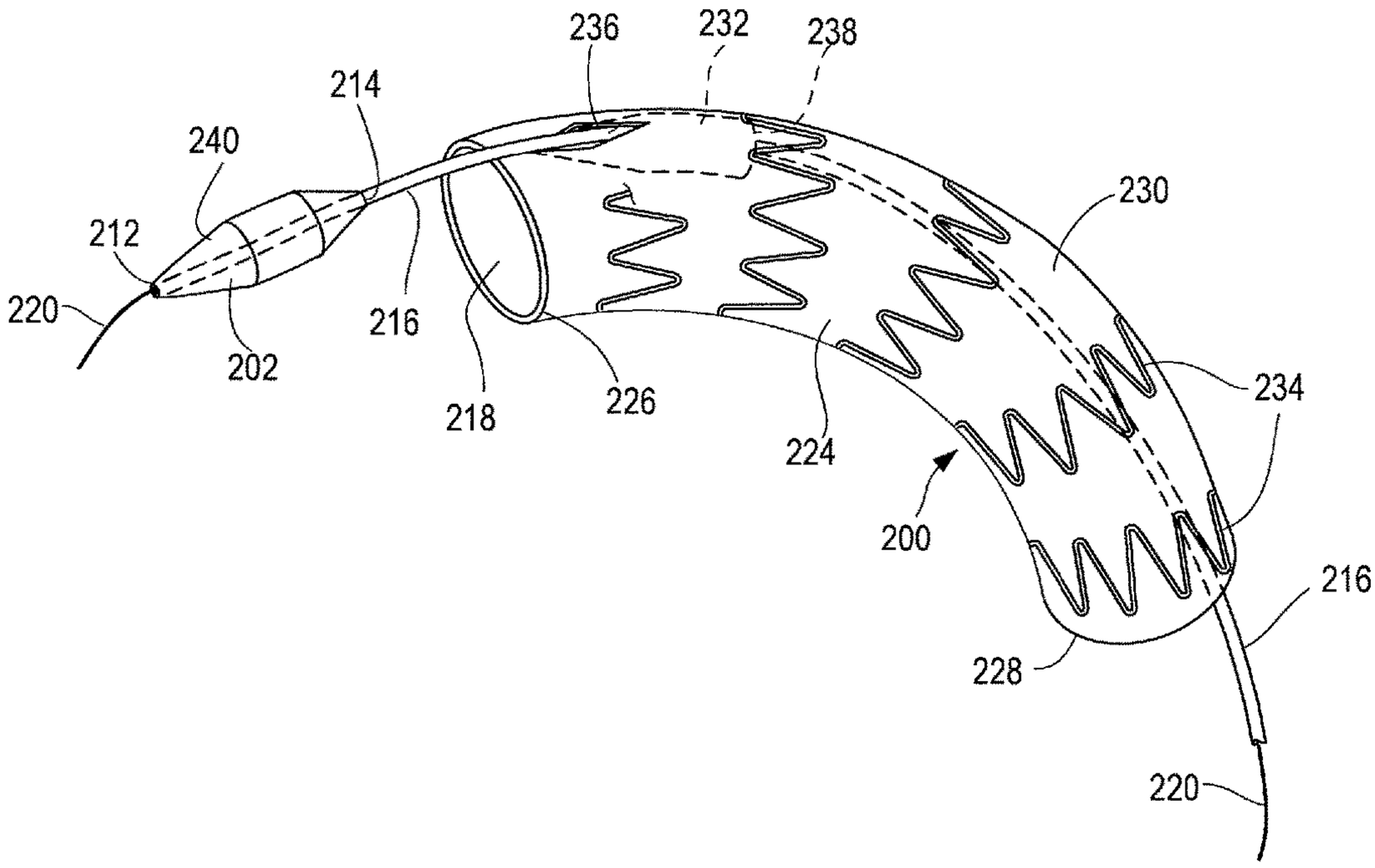


Fig. 8

Fig. 9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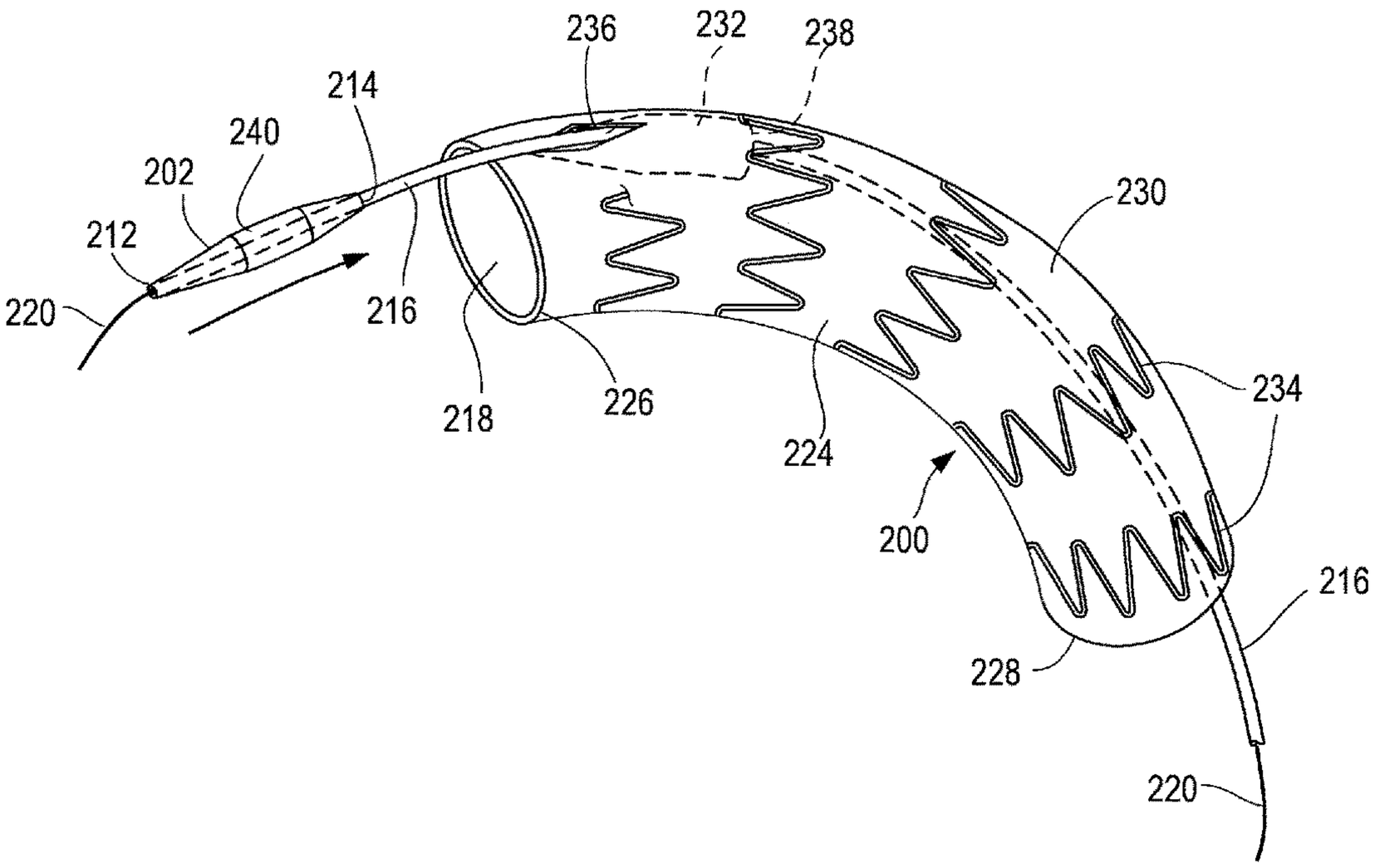
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Fig. 11

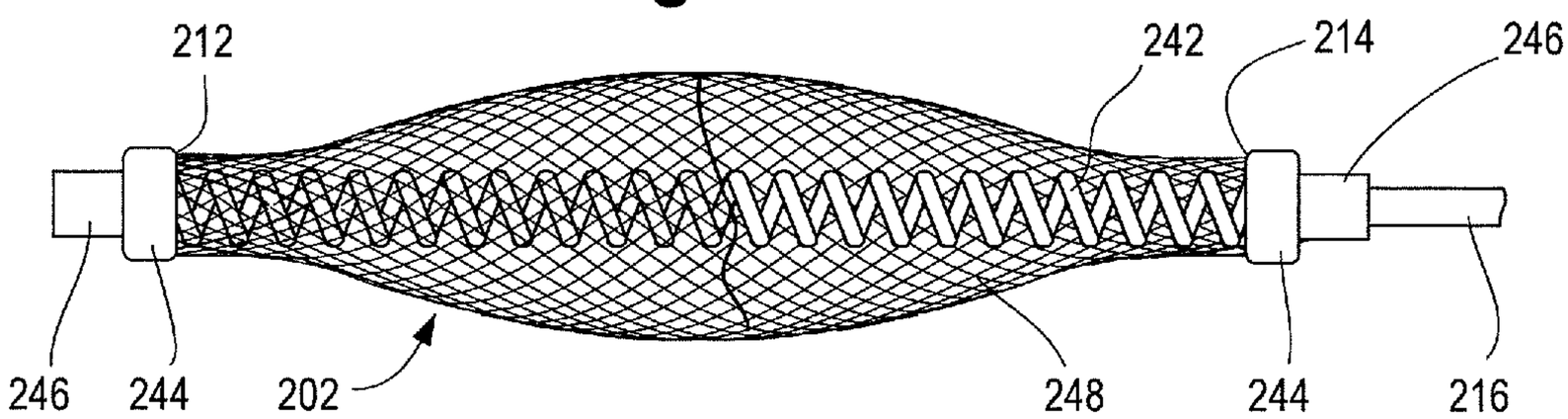
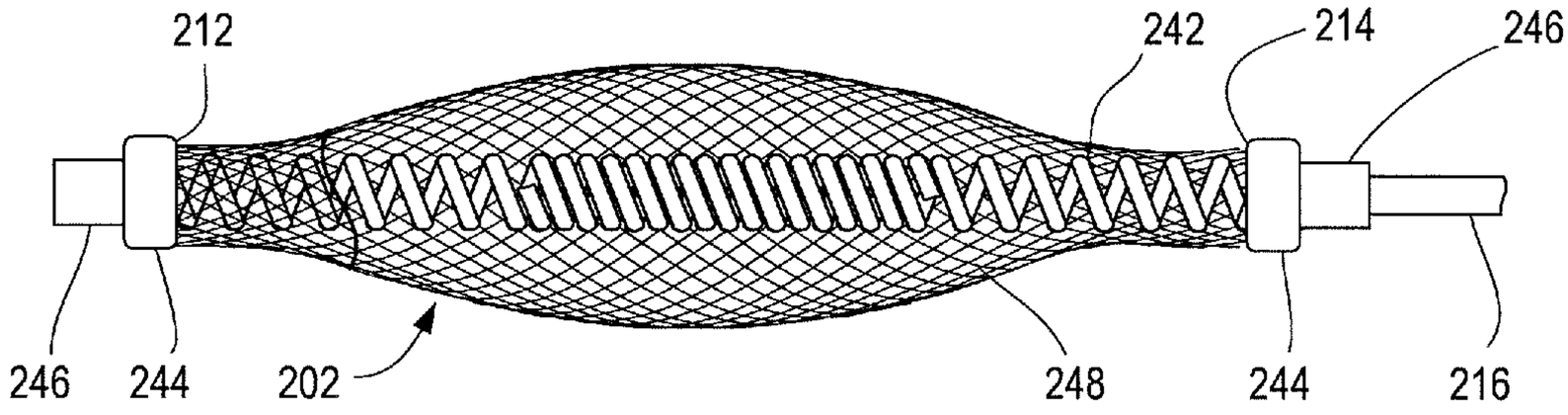


Fig. 11A



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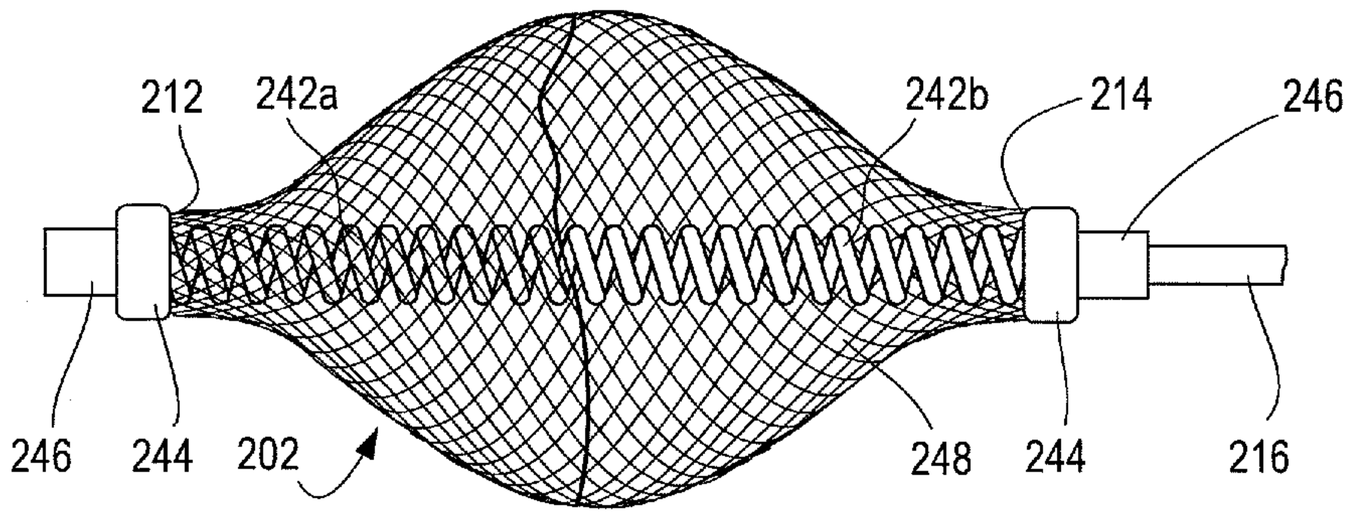

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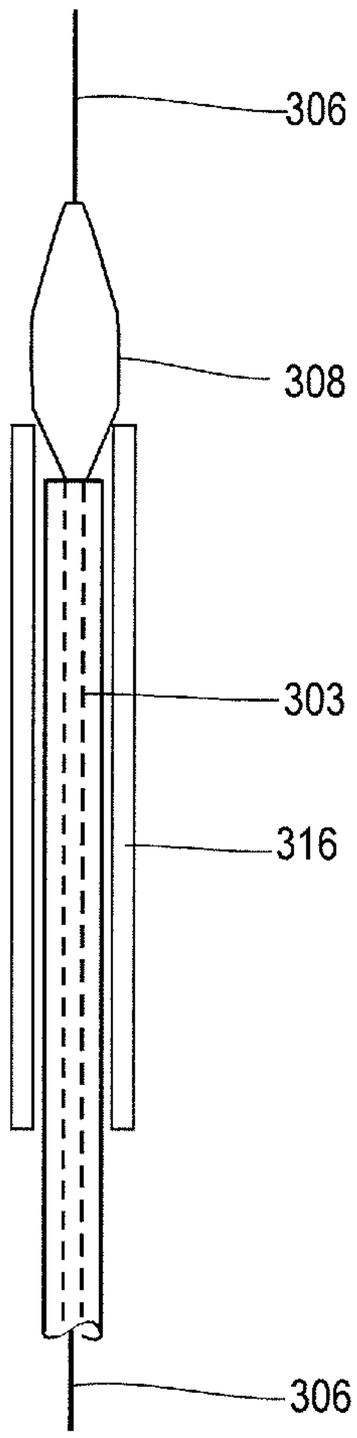

Fig. 14

FIG. 15

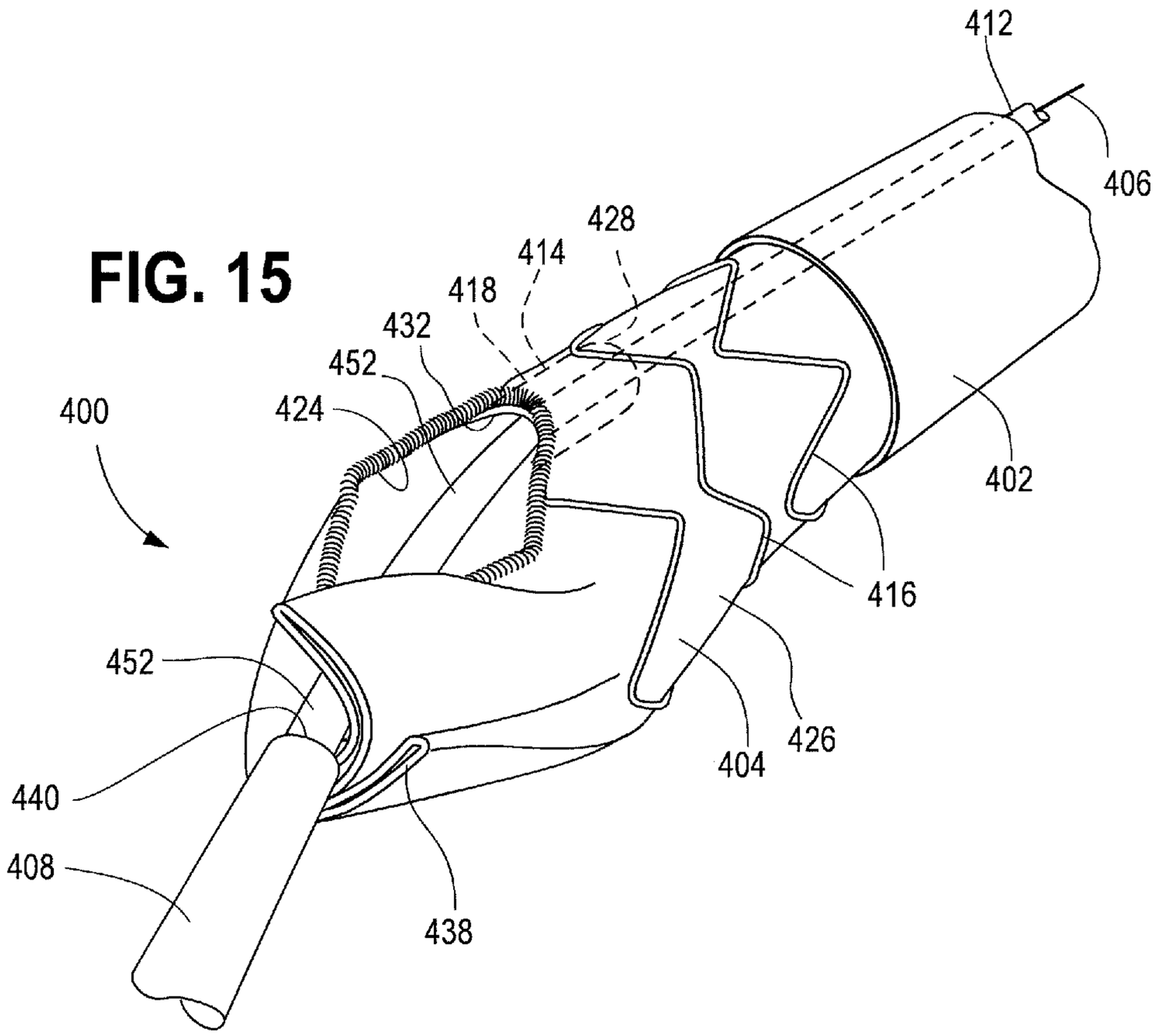
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Fig. 16

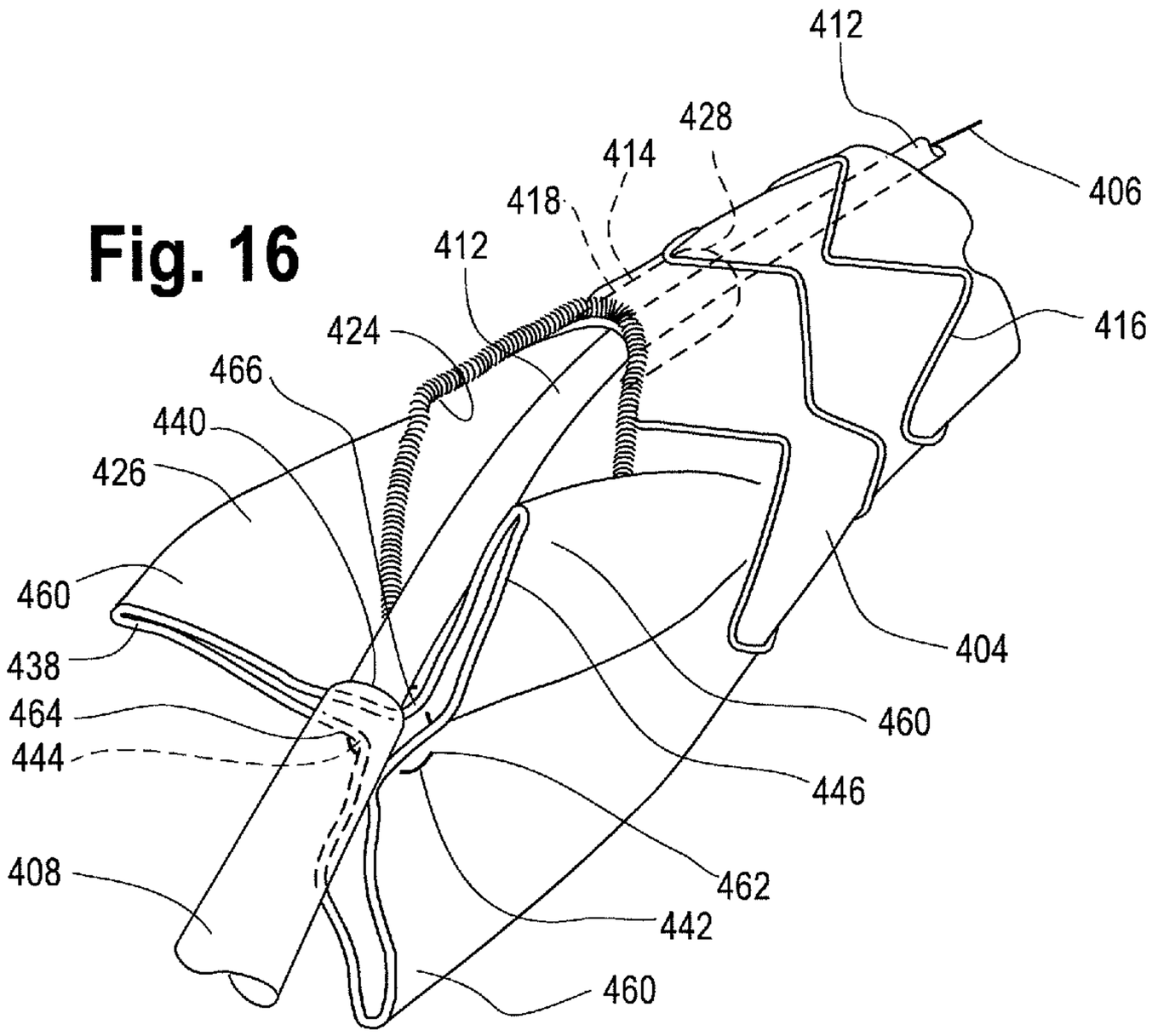
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FIG. 17

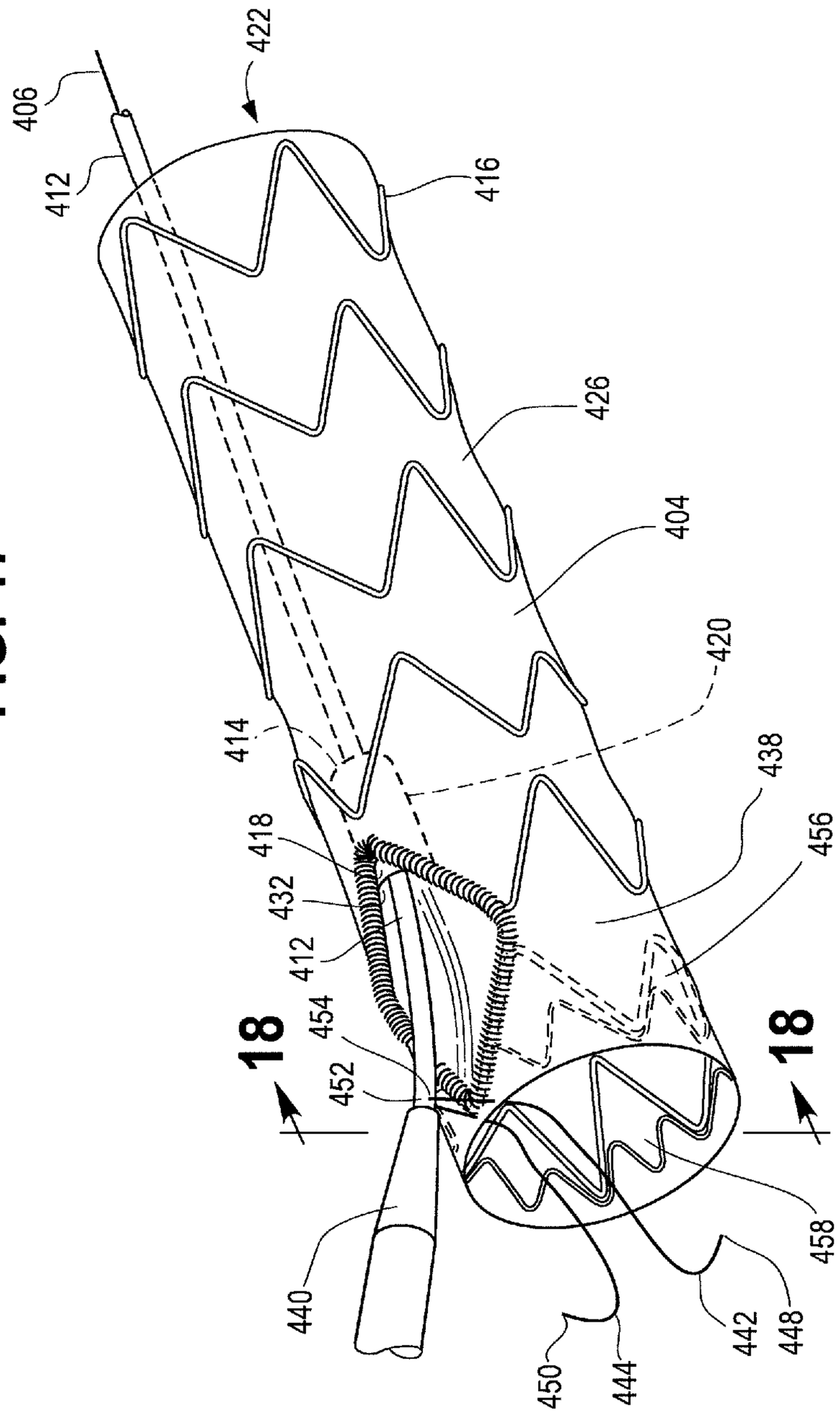
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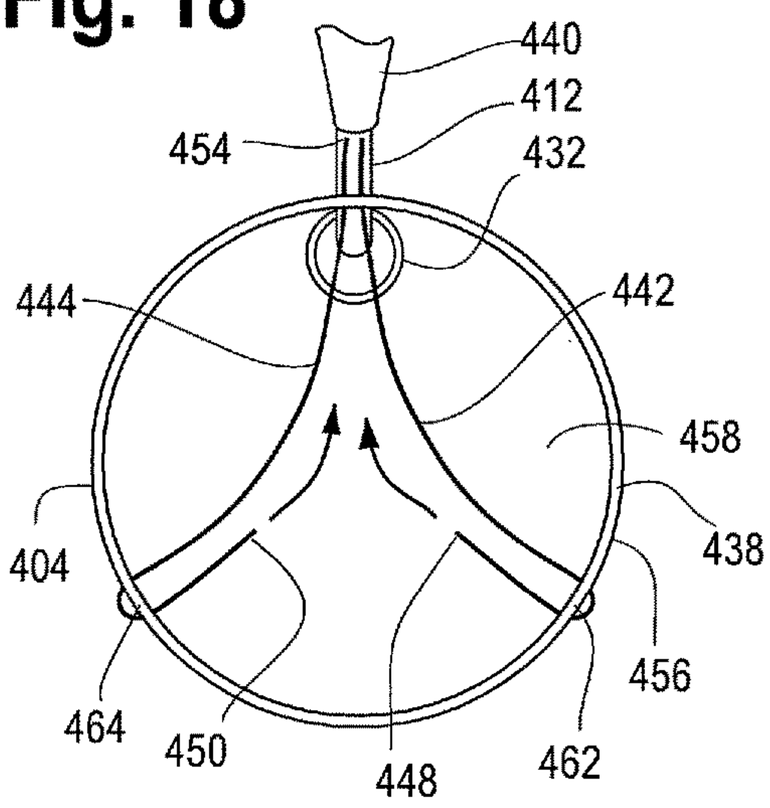
Fig. 18



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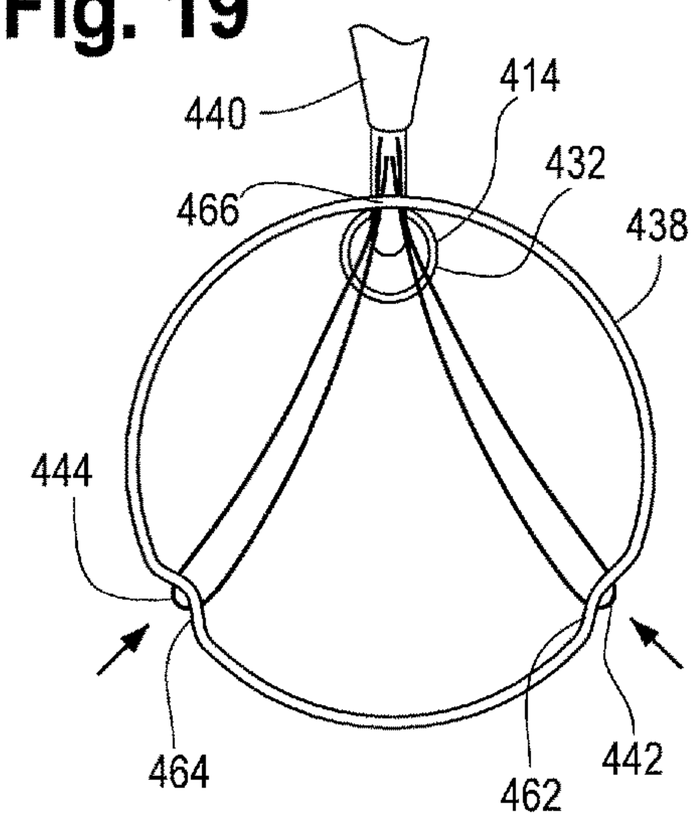

Fig. 20

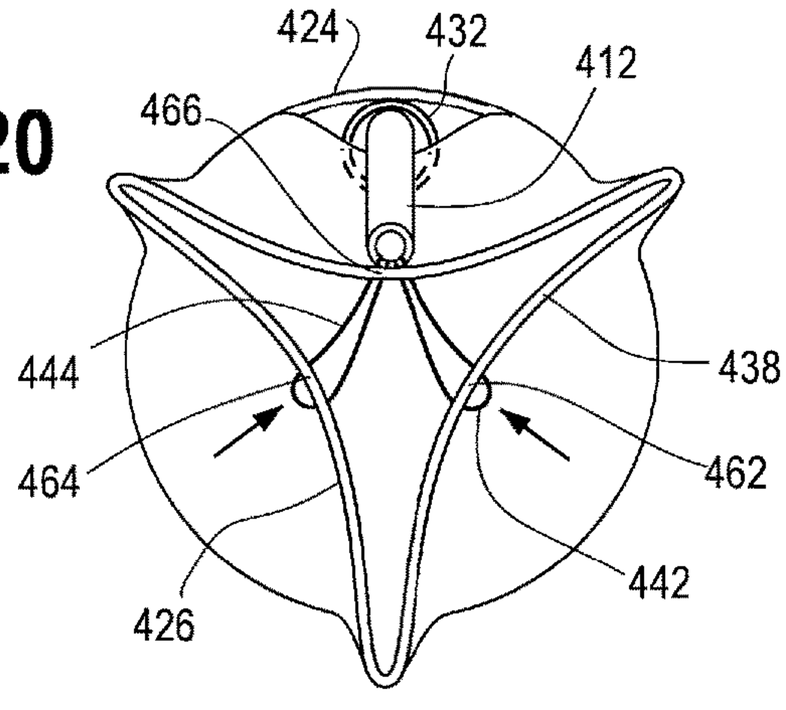

Fig. 21

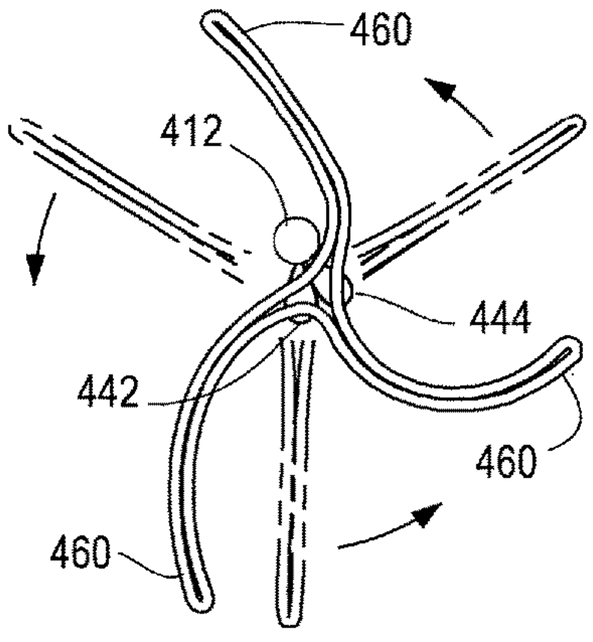

Fig. 22

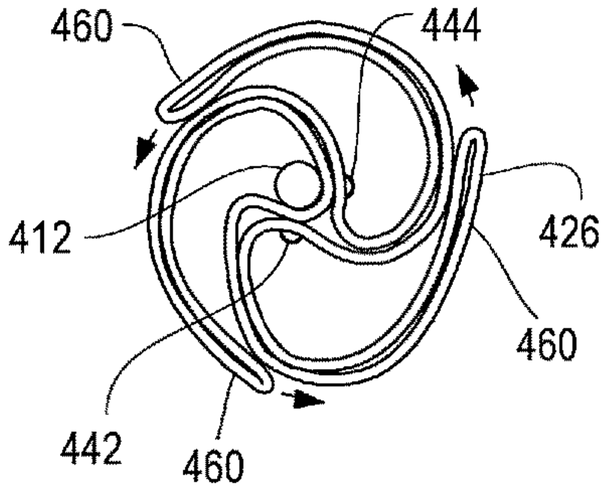

Fig. 23

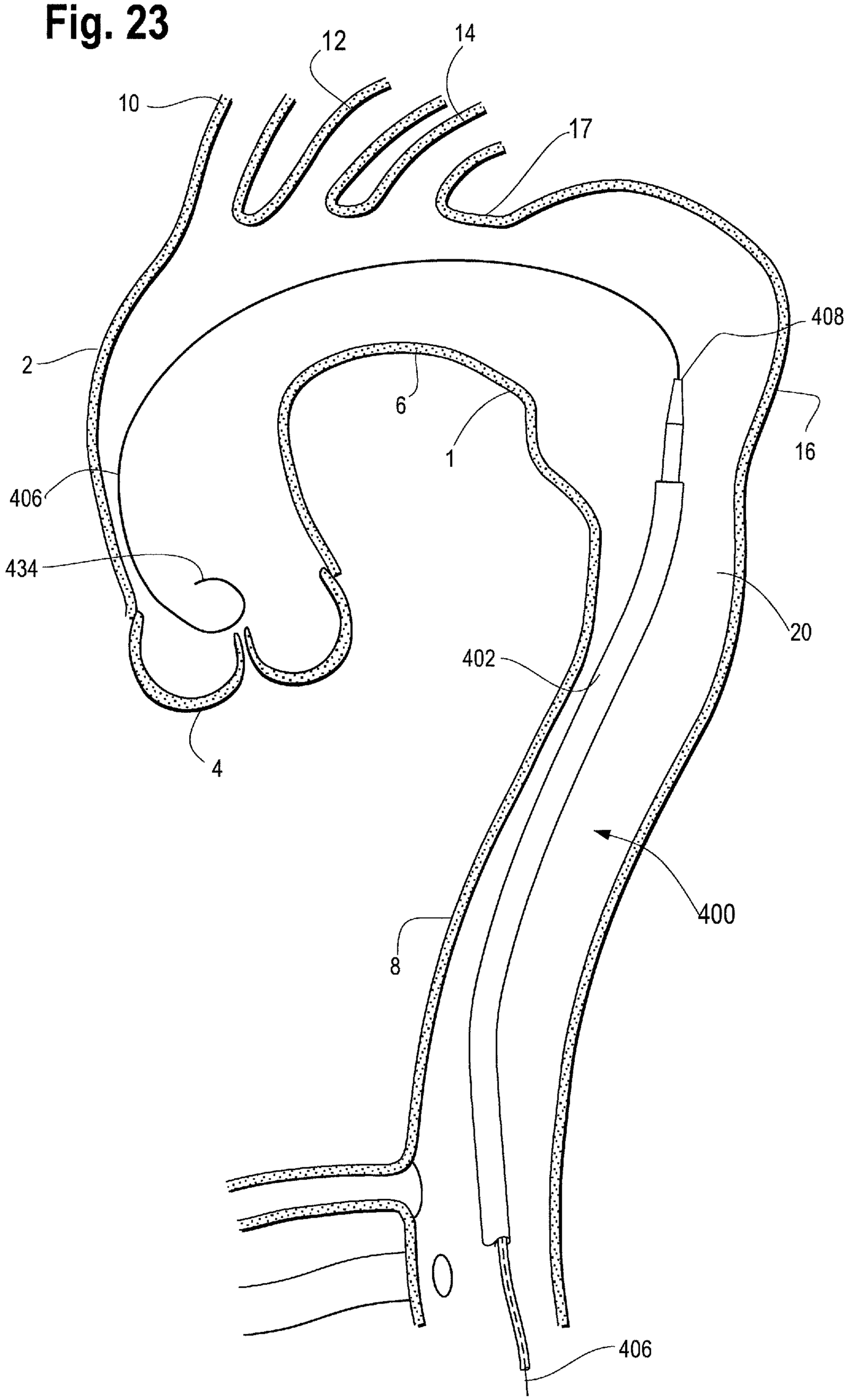

Fig. 24

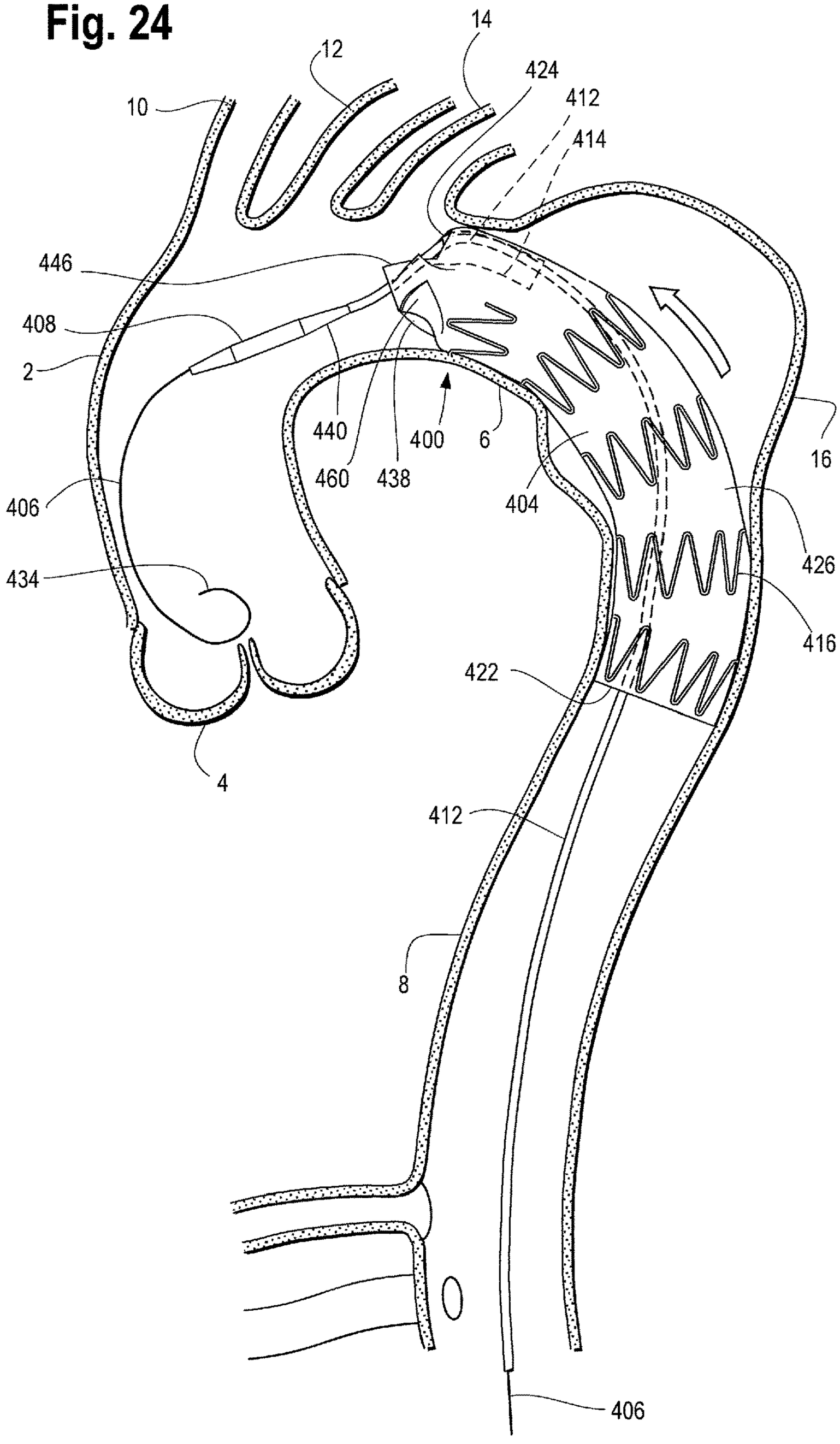
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Fig. 25

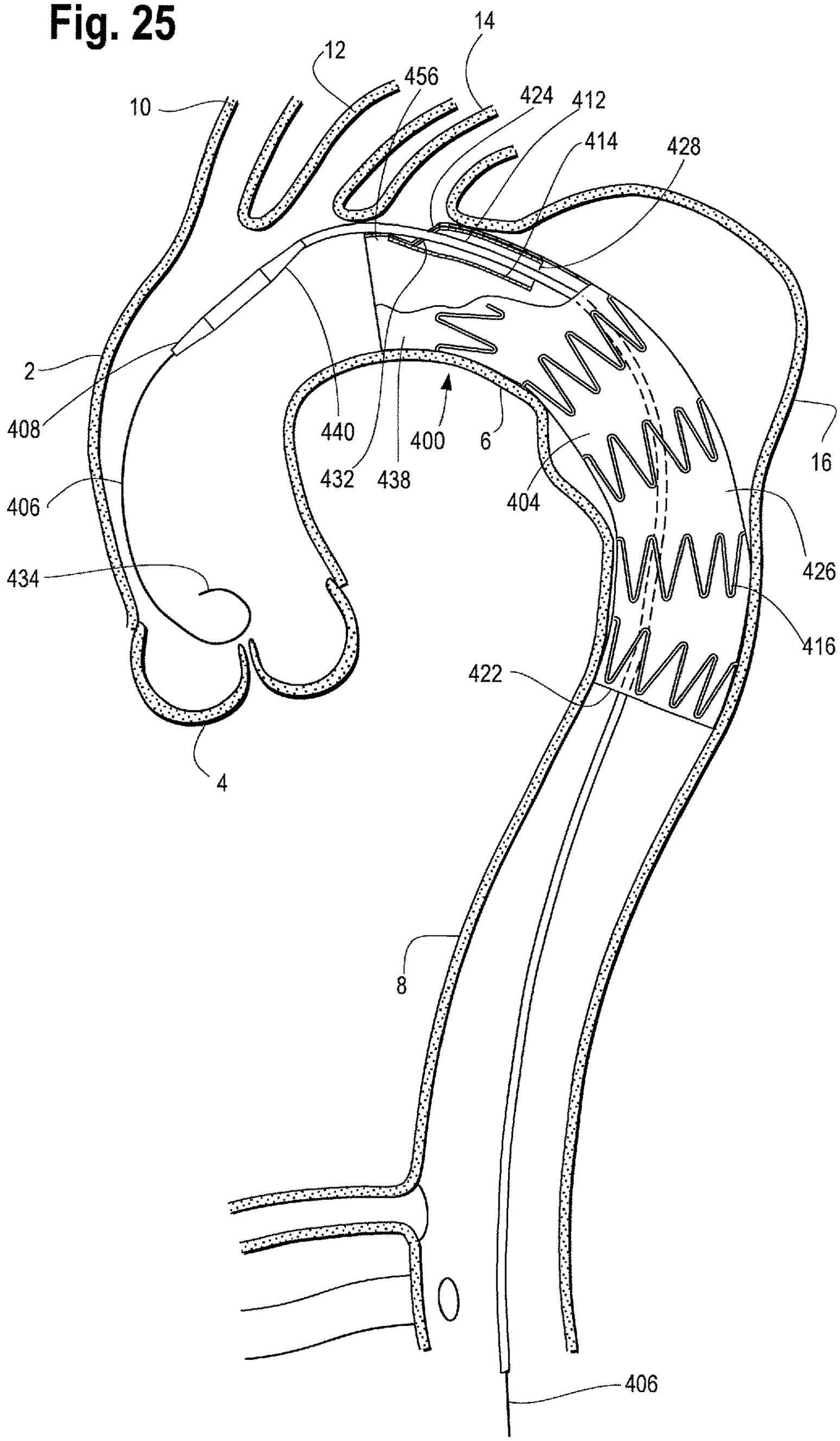
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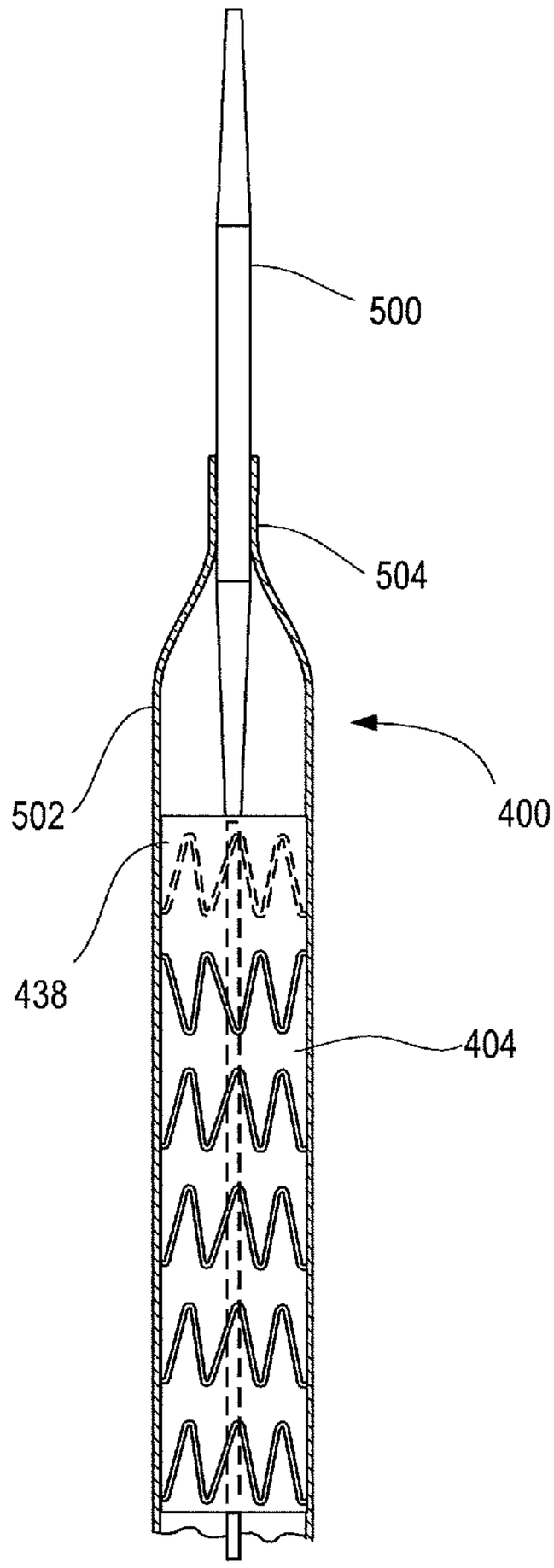
Fig. 26



PRE-LOADED DELIVERY DEVICE WITH TRI-FOLD PROXIMAL PROSTHESIS ATTACHMENT

RELATED APPLICATIONS

This application claims priority to U.S. Provisional application No. 62/128,705, filed on Mar. 5, 2015, and also claims priority to U.S. Provisional application No. 62/148,006 filed on Apr. 15, 2015, which applications are incorporated by reference herein in their entireties.

TECHNICAL FIELD

This disclosure relates to introduction systems for the delivery and deployment of implantable medical prostheses. In particular, this invention relates to a stent graft delivery device or introducer pre-loaded with a guide wire that facilitates both device tracking and cannulation, with a tri-fold attachment mechanism to couple the prosthesis to the delivery device.

BACKGROUND

The introduction and deployment of a medical device such as a stent or stent graft into a patient is a well-known procedure. The introducer may include an external manipulation section or handle, an inner catheter that may accommodate a guide wire, a medical device carried by the inner catheter, a nose cone dilator at the proximal end of the inner catheter and a retractable outer sheath. The medical device is generally coupled to the proximal end of the introducer. During deployment, the medical device is released from the introducer, first by retraction of the sheath, and/or the operation of other release mechanisms to facilitate expansion of the device in the body vessel.

Descending thoracic aortic aneurysms and dissections are often treated by placing a stent graft in the affected region of the vessel. In some procedures, the affected region (i.e., the location of an aneurysm or dissection) necessitates creating a seal with the stent graft at the location of a branch vessel extending from the main vessel, such as the left subclavian artery extending from the aortic arch, for example. In such cases, a fenestrated and/or branched graft may be used to maintain patency of both the main vessel and the branch vessel.

Accordingly, it may be desirable and advantageous to provide a stent graft delivery device or introducer that is pre-loaded with a single guide wire which can facilitate the delivery of the stent graft to the desired location within a vessel as well as the cannulation of one or more branch vessels. It may also be desirable to releasably couple the stent graft to the delivery device with an attachment mechanism including a proximal tri-fold configuration.

SUMMARY

In one example, a prosthesis delivery device is disclosed. The delivery device comprises a delivery catheter having a proximal end and a tubular prosthesis releasably coupled to the proximal end of the delivery catheter. The prosthesis has a proximal end, a distal end, a lumen extending between the proximal end and distal end, a sidewall of graft material, an inner graft surface, an outer graft surface, and a fenestration formed in the sidewall of the prosthesis. The delivery catheter extends proximally through at least a portion of the prosthesis lumen and through the fenestration to a location external of the prosthesis and adjacent a first point on the outer graft surface of the graft at the proximal end. A first proximal attachment mechanism releasably couples a second point on the proximal end of the prosthesis to the delivery catheter, wherein the second point is circumferentially spaced from the first point and a second proximal attachment mechanism releasably couples a third point on the proximal end of the prosthesis to the delivery catheter, wherein the third point is circumferentially spaced from the first point in one direction and from the second point in the opposite direction. The first and second proximal attachment mechanisms draw the second and third points to the first point to form three folds of graft fabric and wherein the folds extend about the delivery catheter in a folded configuration such that the outer surface of the graft at least partially wraps around the delivery catheter.

In another example a prosthesis delivery device is disclosed. The delivery device comprises a delivery catheter having a proximal end and a tubular prosthesis releasably coupled to the proximal end. The prosthesis has a proximal end, a distal end, a lumen extending between the proximal end and distal end, a sidewall of graft material, an inner graft surface, an outer graft surface and a fenestration formed in the sidewall of the prosthesis. The delivery catheter extends proximally through at least a portion of the prosthesis lumen and through the fenestration to a location external of the prosthesis and adjacent a first point on the outer graft surface at the proximal end of the prosthesis. A first proximal attachment mechanism releasably couples a second point on the proximal end of the prosthesis to the delivery catheter, wherein the second point is circumferentially spaced from the first point and a second proximal attachment mechanism releasably couples a third point on the proximal end of the prosthesis to the delivery catheter, wherein the third point is circumferentially spaced from the first point in one direction and circumferentially spaced from the second point in the opposite direction. The first and second proximal attachment mechanisms draw the second and third points to the first point to form first, second, and third folds of graft fabric and wherein the folds extend about the delivery catheter in a folded configuration.

In yet another example, a prosthesis delivery device is disclosed. The delivery device comprises a delivery catheter having a proximal end and a tubular prosthesis releasably coupled to the proximal end of the delivery catheter. The prosthesis has a proximal end, a distal end, and a lumen extending between the proximal end and distal end and a fenestration formed in a sidewall of the prosthesis. The delivery catheter extends proximally though at least a portion of the prosthesis lumen and through the fenestration formed in the side sidewallwall of the prosthesis. A first attachment mechanism releasably couples a second point at the proximal end of the prosthesis to the delivery catheter and a second attachment mechanism releasably couples a third point at the proximal end of the prosthesis to the delivery catheter. The first and second proximal attachment mechanisms have a first configuration in which the proximal end of the prosthesis is coupled to the delivery catheter and a second configuration in which the proximal end of the prosthesis is released from the delivery catheter.

BRIEF DESCRIPTIONS OF THE DRAWINGS

FIG. **1** shows an example of an introducer located within a vessel.

FIG. **2** shows an example of an introducer located within a vessel and an example of a branched stent graft deployed therein.

FIG. **3** shows the proximal end of the introducer of FIG. **2** with one example of a deployed branched stent graft having a catheter and a guide wire extending proximally through a portion of the stent graft and into a channel formed in the nose cone dilator.

FIG. **4** shows the proximal end of an introducer with one example of a deployed fenestrated stent graft having a catheter and a guide wire extending proximally through a portion of the stent graft and into a channel formed in the nose cone dilator.

FIG. **5** shows the introducer of FIG. **3** where the catheter and guide wire have been distally retracted out of the channel formed in the nose cone dilator.

FIG. **6** shows the introducer of FIG. **4** where the catheter and guide wire have been distally retracted out of the channel formed in the nose cone dilator and a secondary guide wire remains in a straight lumen of the nose cone dilator.

FIG. **7** shows an enlarged view of a nose cone dilator with a catheter and guide wire extending through a curved channel and a straight lumen extending through the nose cone.

FIG. **8** shows one example of a conventional introducer.

FIG. **9** shows an introducer with a deployed branched stent graft and a variable diameter dilator tip in an expanded-diameter configuration.

FIG. **10** shows the introducer of FIG. **9** with a deployed branched stent graft and a variable diameter dilator tip in a reduced-diameter configuration.

FIG. **11** shows another example of a variable diameter tip in a reduced-diameter configuration with a single resilient elongated member.

FIG. **11**A shows another example of a variable diameter tip in a reduced-diameter configuration with two resilient elongated members.

FIG. **12** shows the variable diameter dilating tip of FIG. **11** in an expanded diameter configuration.

FIG. **13** illustrates a dilator and a delivery sheath that may be placed within a vessel during a procedure utilizing a cartridge technique.

FIG. **14** shows another example of an introducer with a peel-away sheath that may be tracked through the delivery sheath of FIG. **13** in a procedure utilizing a cartridge technique.

FIG. **15** shows an example of a stent graft coupled to the proximal end of an introducer and partially constrained by an introducer sheath.

FIG. **16** is a perspective view of the proximal end of the introducer with the stent graft releasably coupled to the introducer using a tri-fold configuration.

FIGS. **17-22** illustrate one example of a method for using two wires as a proximal attachment mechanism to create a tri-fold configuration at the proximal end of a stent graft to releasably couple the stent graft to the introducer.

FIG. **23** shows the introducer of FIG. **15** with the stent graft covered by a sheath and being tracked over a guide wire in a curved vessel.

FIG. **24** shows the introducer of FIG. **23** with the sheath fully withdrawn.

FIG. **25** shows the introducer of FIG. **24** with the proximal attachment wires removed to release the proximal tri-fold configuration and uncouple the proximal end of the stent graft from the introducer.

FIG. **26** shows an example of an introducer assembly with a sheath tapered radially inwardly at the proximal end to mate with a nose cone dilator.

DETAILED DESCRIPTION

The present disclosure relates to a delivery device or introducer for delivering a prosthesis such as a radially expandable stent graft within a human or animal body for repair of damaged vessels, ducts, or other physiological pathways and systems. In the present disclosure, the term "proximal" refers to a direction that is away from a physician during a medical procedure, while the term "distal" refers to a direction that is closest to the physician during the procedure. In addition, like reference numbers throughout the various drawings designate similar structure.

FIG. **1** shows an example of an introducer that has been tracked over a guide wire to a desired location within a curved vessel. In FIG. **1**, the curved vessel **1** is the thoracic aorta. The thoracic aorta includes the ascending aorta **2** extending from the aortic valve **4** of the heart of the patient, the thoracic arch **6** and the descending aorta **8**. Three branch arteries extend from the main artery (the thoracic arch **6**) including the innominate artery **10**, the left carotid artery **12** and the left subclavian artery **14**. As shown, an aneurysm **16** has developed just distal of the left subclavian artery **14**. The space **17** between the most proximal portion of the aneurysm **16** and the left subclavian artery **14** may, in some cases, be relatively short as shown in FIG. **1**, and in other cases the space may be longer. Depending on the patient's unique anatomy and the location of the aneurysm **16**, it may be necessary to extend the proximal end of a stent graft deployed in the vessel lumen **20** to an area or location that is proximal of the left subclavian artery **14** but distal to the left carotid artery **12**. In doing so, blockage of some or all of the left subclavian artery **14** by the body of the stent graft may result. Accordingly, it may be advantageous to provide an introducer that is pre-loaded with a guide wire and a stent graft to facilitate cannulation of a branch vessel (such as the left subclavian artery **14**) to therefore maintain/restore patency to the main vessel and branch vessels. As described herein, the stent graft carried on the introducer is preferably pre-cannulated with the guide wire. This single guide wire facilitates tracking of the introducer within a vessel, cannulation of the stent graft carried on the introducer and also allows cannulation of one or more of the branch vessels during use.

As partially shown in FIG. **1**, an introducer **18** has been advanced into the lumen **20** of the vessel **1**. In one example, the introducer **18** includes a retractable or removable sheath **22** and a secondary catheter **74**. One or more guide wires **26** may extend through the lumen of the secondary catheter **74**. The secondary catheter may be straight and/or it may have a curve imparted to a portion of it. For example, the secondary catheter **74** may be curved at a proximal end, with the curve of the secondary catheter generally corresponding to the outer or greater portion of the curve of the aortic arch **6**.

The guide wire **26** may first be introduced into the vessel **1** and the introducer **18** then tracked over the guide wire **26** to a desired position within the vessel. Alternatively, the guide wire **26** may be pre-loaded within the secondary catheter **74** of the introducer, and thereby inserted into the vessel simultaneously with the introducer **18**, or in yet a further example, the guide wire **26** may be inserted through the secondary catheter **74** of the introducer **18** and into the vessel **1** after the introducer has been at least partially

positioned in the vessel **1**. The introducer **18** also includes a nose cone dilator **28** extending proximally from the proximal end of the delivery catheter **66**. The nose cone dilator **28** may be tapered and/or flexible to present an atraumatic tip.

As shown, the guide wire **26** extends through the secondary catheter **74** of the introducer **18**, through at least a portion of the nose cone dilator **28** and has been extended further proximally to extend from the tip **30** of the nose cone dilator **28**. As such, the guide wire **26** may facilitate tracking of the delivery device for placement, adjustment and movement of the delivery device **18** within the vessel **1**. The proximal tip **32** of the guide wire **26** may have a curved (pig-tailed end) atraumatic tip so as not to pierce or damage the walls of the vessel lumen **20** and/or the aortic valve **4**. The introducer **18** can be substantially straight or it may have a curved configuration imparted at its proximal end as described in U.S. Pat. No. 8,394,135, which is incorporated by reference herein. The nose cone dilator **28** also may be straight or curved, as shown in FIGS. 9 and 10 of U.S. Publication Application No. 2011/0125244 and in U.S. Pat. No. 7,611,529, which are both incorporated by reference herein. Prior to and during delivery of a prosthesis, such as a stent graft **34**, the sheath **22** extends proximally to cover the stent graft **34** carried on introducer **18** to hold the stent graft in a radially inwardly contracted delivery configuration. The sheath **22** may extend proximally to cover at least the distal end of the nose cone dilator **28** as illustrated in FIG. **1**.

FIG. **1** shows an example of an introducer **18** tracked over guide wire **26** to a location within a vessel **1**, with the stent graft **34** still covered and held in a radially inwardly contracted delivery configuration by sheath **22**. FIG. **2** shows the introducer of FIG. **1** within the vessel **1** after the sheath **22** has been distally retraced allowing the stent graft **34** to deploy from the introducer **18** and become expanded within the vessel **1** at the site of aneurysm **16**. As shown, the stent graft **34** has a proximal end **36**, a distal end **38**, a proximal opening **40**, a distal opening **42** and a tubular body **44** extending between the proximal **36** and distal **38** ends to define a graft lumen **52**. The stent graft **34** may be a generally singular tube-like configuration with an internal branch **48** extending within the lumen **52** of the graft body **44** as illustrated in FIG. **2**, although other configurations are also contemplated. For example, the stent graft **34** may be a fenestrated stent graft (wherein one or more openings or fenestrations are formed in the graft body **44**) and/or a bifurcated stent graft (with first and second legs extending from the main graft body).

A series of stents **46** may be attached to the graft body **44** and extend along all of, or at least part of, the length of the stent graft **34**. An exposed anchoring stent (not shown) with one or more barbs for attaching the stent graft to a vessel wall may extend from the proximal end **36** of the graft body **44** as described in U.S. Publication Application No. 2012/0277848, which is incorporated by reference herein. The stents **46** may be sutured to the graft material or held to the graft material in other known ways. The series of body stents **46** may be internal or external to the graft body **44**, or both. For example, one of the stents **46** near the proximal end **36** and/or the distal end **38** of the stent graft **34** may be an internal sealing stent while the remaining body stents **46** are external to the graft body **44**. Any one or more of the stents **46** may be provided with barbs that extend from the stent inside the tubular graft body, through the graft material to engage the vessel wall. Radiopaque markers (not shown) may be placed on various parts of the stent graft **34** to aid the user in positioning the stent graft during deployment.

Stents **46** may be zig-zag shaped as shown in FIG. **2**, although other stent configurations are known and may be used alone or in combination with the zig-zag stents **46** and/or have other configurations as known in the art. The stents may be constructed of a self-expanding shape memory material, such as Nitinol, or they may be balloon expandable, or a combination of both depending on the particular characteristics desired of the stent graft.

As shown in FIG. **2**, stent graft **34** is a branched stent graft that has been deployed in the aorta **1**, having a series of self-expanding stents **46** extending along the length of the graft body **44**. In this example, the branch **48** is an internal branch. In other words, the body **50** of the branch **48** extends within the lumen **52** of the stent graft **34**. The branch **48** has a proximal end that extends from an aperture **56** formed in the sidewall of the graft body **44** and has a distal open end **54** that opens into lumen **52** of the stent graft **34**.

FIG. **3** and FIG. **4** illustrate an introducer **18** with one example of a nose cone dilator **28** and a fully deployed stent graft **34**. The nose cone dilator **28** has a distal end **58** and a proximal end **60** and a sidewall **62** extending between the proximal and distal ends. Nose cone dilator **28** may have a straight or substantially straight lumen **64** formed within and extending the length of the nose cone dilator **28** between the distal end **58** and proximal end **60**. The straight lumen **64** may be configured to receive one or more guide wires and/or catheters there through. In one example, straight lumen **64** receives at least a proximal end of delivery catheter **66** but does not receive a guide wire. The delivery catheter **66** may be straight and/or it may have a curve imparted to a portion of it. For example, the delivery catheter **66** may be curved at a proximal end, with the curve of the secondary catheter generally corresponding to the outer or greater portion of the curve of the aortic arch **6**.

Nose cone dilator **28** may also have a channel **68** formed within and extending through a portion of the length of the nose cone dilator **28** from the proximal end **60** and to the aperture **70** formed in the sidewall **62**. The channel **68** may be at least partially curved and extend from the proximal end **60** of the nose cone dilator **28** and exit from the nose cone through the sidewall **62** of the nose cone dilator at aperture **70**, as shown in FIG. **4**. In one example, channel **68** may extend substantially longitudinally for a distance (i.e., substantially parallel to straight lumen **64**) and then curve at its distal end to exit the sidewall **62** of the nose cone dilator **28** through aperture **70** at a location approximately midway between the proximal end **60** and distal end **58** of the nose cone dilator **28** as shown in FIGS. **3** and **4**. However, the curved channel may exit the nose cone dilator **28** either closer to the proximal end **60** or closer to the distal end **58**. In another example, the channel **68** may have a curve imparted to its entire length or may have a helical shape imparted to it.

In an alternative example (not shown), the curved channel **68** may be in the form of an elongated opening or slot extending from the aperture **70** formed in the sidewall **62** of the nose cone dilator **28** towards the proximal end **60**. The channel or slot may be straight or curved or a combination thereof, and extend partially or, alternatively, extend all the way to the proximal end **60** of the nose cone dilator **28**. In yet a further example, a groove (not shown) formed in the surface of the nose cone sidewall **62** may be used in place of the curved channel **68**. The channel **68** (and/or slot or groove) may extend partially and/or fully in a proximal direction from a point of origination (such as aperture **70** and/or the beginning of the groove) towards the proximal end **60** of the nose cone. The channel **68** (or slot or groove)

is preferably shaped and configured to receive at least a portion of the guide wire **26** and/or the secondary catheter **74** therein.

In another example, either alone or in combination with the above, a trigger wire (not shown) may also be provided to constrain the proximal tip of the guide wire **26** and/or the secondary catheter **74** against or within the nose cone dilator **28**. More specifically, one or more trigger wires may be used to retain the guide wire **26** and/or the secondary catheter **74** within the curved channel **68** (or within the above-described alternatives, including the elongated opening, slot or groove formed in the nose cone dilator **28**). The one or more trigger wires may pass over the secondary catheter **74** (and/or the guide wire **26** extending through the secondary catheter **74**) at one or multiple points along its length and secure it to the nose cone dilator **28**. Thus, when the trigger wire(s) is removed, the secondary catheter **74** (and guide wire **26**) are freed from the nose cone dilator **28** and can then be manipulated by the user to make any necessary exchanges, including, but not limited to cannulating a side vessel (such as the left subclavian artery) extending from the aorta **1**. When only trigger wire(s) are used to secure the secondary catheter **74** to the nose cone dilator **28** (and the secondary catheter **74** is not constrained within the curved channel **68** or above-described slot), it may not be necessary to distally retract the secondary catheter **74** to free it from a constrained configuration within the channel **68**. Instead, removal of the trigger wire(s) will free the secondary catheter **74** from the nose cone dilator **28** so that it is available for further manipulation by the user.

Secondary catheter **74** can be preloaded with guide wire **26** extending there through. Alternatively, guide wire **26** may first be inserted into the vasculature and the introducer **18** then tracked over the guide wire **26**, through secondary catheter **74**, and into position within the vessel. In a non-limiting example, one procedure for introducing the introducer **18** into a patient is by means of the well-known Seldinger technique, in which a guide wire **26** is first inserted percutaneously into a patient's vasculature via a needle (not shown). The introducer **18** is inserted percutaneously and endoluminally into the patient, by tracking it over the guide wire **26**, which acts to guide the introducer **18** through the vasculature up to the treatment site.

In one example, the straight lumen **64** and curved channel **68** create a 'Y" shape within the nose cone dilator **28**. In other words, as shown generally in FIGS. **5** and **6**, the straight lumen **64** lies in a relatively straight line from the proximal end **60** to the distal end **58** of the nose cone dilator **28** and the curved channel **68** intersects the straight lumen **64** at some point between the proximal end **60** and the distal end **58** of the nose cone dilator **28** to generally form a "Y" configuration. In one example, the curved channel **68** intersects the straight lumen **64** about half way between the proximal end **60** and the distal end **58** of the nose cone dilator **28**, although, the channel **68** may intersect the straight lumen **64** closer to the proximal end **60** and/or closer to the distal end **58** of the nose cone dilator **28**.

As shown in FIGS. **3** and **4**, the stent graft **34** carried by the introducer **18** can be pre-loaded with the guide wire **26**. In one example, the guide wire **26** can extend proximally through the lumen **52** of the graft body **44**, into the distal end **54** of the internal branch **48** and exit out of the branch **48** at proximal branch opening **56**. The proximal tip **32** of the guide wire **26** can extend through channel **68** of the nose cone dilator **28** and into the proximal end **60** of the nose cone dilator **28**. As shown in FIGS. **1** and **2**, the guide wire **26** can, in use, be proximally advanced all the way out of the proximal end **60** of the nose cone dilator **28**.

Secondary catheter **74** may be coaxial with at least a portion of the guide wire **26**. In one example, the secondary catheter **74** is also pre-loaded within the introducer **18**, such that the secondary catheter **74** is coaxial with and extends proximally over the guide wire **26**, through the lumen **52** of the graft body **44**, into the distal end **54** of the internal branch **48**. The secondary catheter **74** then exits out of the branch **48** at proximal branch opening **56**. As FIG. **2** shows, the proximal end **76** of the secondary catheter **74** can be tucked into and held within the curved channel **68** of the nose cone dilator **28**. As shown in FIGS. **3** and **4** (and shown in greater detail in FIG. **7**) the curved channel **68** (**168** of FIG. **7**) may have a substantially constant inner diameter along its length, and near the proximal end **60** of the nose cone dilator **28**, the inner diameter of the channel **68** (**168**) becomes narrowed at point **69**. In this way, the secondary catheter **74** (**174**) can advance proximally through the channel **68** (**168**) to the proximal end **60** of the nose cone dilator **28** but it cannot advance through the narrowed inner diameter portion **69** of the channel **68**. While the guide wire **26** (**126**) may pass through the narrowed diameter portion **69** of the channel **68**, the secondary catheter **74** cannot pass through this narrowed diameter portion **69** of the channel **68** and is therefore prevented from extending proximally out of the proximal tip **30** (**130**) of the nose cone dilator **28**.

As shown partially in FIG. **1**, the delivery catheter **66** may extend proximally from an external manipulation handle section or distal end of the introducer **18** (identified as reference number **100** in FIG. **8**) through the lumen **52** of the graft body **44** and into the straight lumen **64** of the nose cone dilator **28** to secure the nose cone dilator **28** to the proximal end of the delivery catheter **66**. The delivery catheter **66** may terminate within the lumen **64** near the distal end **58** of the nose cone dilator **28**, or alternatively, the delivery catheter **66** may extend further into the lumen **64** and terminate at a point closer to the proximal end **60** of the nose cone dilator **28**.

As shown in FIGS. **1** and **2**, the guide wire **26** advantageously serves as a means to track the introducer **18** to a desired location within the vessel **1** while also pre-cannulating the branch **48** of the stent graft **34** with a single wire **26**. In other words, introduction of the introducer and cannulation of the branch **48** may be combined through the use of a single guide wire **26**, and this same guide wire may then be further manipulated during use to cannulate one or more branch vessels extending from the main vessel.

In one example, as FIG. **1** shows, a guide wire **26** can be inserted percutaneously and advanced proximally through a vessel. Next, the introducer **18** containing a prosthesis (such as a stent graft **34** held in a radially compressed delivery configuration under a sheath **22**) can be advanced over the guide wire **26**. When the prosthesis is in a deployment position within a vessel lumen **52**, the sheath **22** can be withdrawn and the stent graft **34** can be deployed by one or more known methods. For example, following sheath retraction, one or more trigger wires or diameter reducing ties (wires **442**, **444** described in detail below in connection with FIGS. **15-25**) at the proximal end **36** of the stent graft **34** and/or the distal end **38** of the stent graft, or both ends, can be removed allowing the stent graft **34** to radially outwardly expand and deploy from the introducer **18**. With the secondary catheter **74** and/or the delivery catheter **66** having a curve imparted to at least a proximal end or portion of it (which curve generally corresponds to the outer curve of the aortic arch **6**) the secondary catheter **74** and/or the delivery

catheter **66** tend to sit adjacent to or on the greater curve of the aorta. With the stent graft **34** properly aligned with any one or more of the desired branch vessel(s), the stent graft **34** will preferably open away from the delivery catheter **66** as it is unsheathed during deployment, further guaranteeing proper orientation within the vessel.

FIG. **4** and FIG. **6** show an example of the proximal end of an introducer **18** with another example of a stent graft **78** carried on the introducer **18**. The stent graft shown in FIGS. **4** and **6** is a fenestrated stent graft **78** that has been deployed within a vessel **1**. Fenestrated stent graft **78** has at least one fenestration or opening **80** formed in the sidewall of the graft body **44**, but may not have the internal branch **48** as does the stent graft **34** shown in FIGS. **3** and **5**. A guide wire **26** can be threaded proximally through the lumen **52** of the graft **78** and extended out of the lumen **52** through the fenestration **80**. The proximal tip **32** of the guide wire **26** can then be threaded into and through the curved channel **68** of the nose cone dilator **28** as shown in FIG. **4**. The guide wire **26** can advance into the proximal end **60** of the nose cone dilator **28** and be further advanced proximally all the way out of the proximal end **60** of the nose cone dilator **28**.

As also shown in FIG. **4**, the secondary catheter **74** is coaxial with at least a portion of the guide wire **26**. In one example, the secondary catheter **74** is pre-loaded within the introducer **18**, such that the secondary catheter **74** extends proximally over the guide wire **26** and through the lumen **52** of the graft body **44**, and exits out of the graft lumen **52** through fenestration **80**. The proximal end **76** of the secondary catheter **74** can be tucked into and held within the curved channel **68** of the nose cone dilator **28**. The secondary catheter **74** can advance towards the proximal end **60** of the nose cone dilator **28** but it cannot advance all the way out of the proximal end **60** of the nose cone dilator **28** due to the narrowed inner diameter portion **69** of the channel **68**. Like FIGS. **1-3**, the guide wire **26** of FIGS. **4** and **6** also advantageously serves as a means to track the introducer **18** to a desired location within the vessel while also pre-cannulating the fenestration **80** with a single wire **26**. In other words, the stent graft **78** is pre-cannulated within the introducer by the guide wire **26** (i.e., the wire extends through the graft lumen and fenestration **80**), and in addition, the guide wire allows the introducer to be tracked into place within a vessel while also allowing the wire to be manipulated in use to cannulate a branch vessel, as described below.

FIGS. **5** and **6** show the guide wire **26** and secondary catheter **74** retracted partially distally. The proximal tip **32** of the guide wire **26** has been withdrawn distally from the nose cone dilator **28**. In addition, the secondary catheter **74** has been retracted distally so that it is no longer constrained within the channel **68** of the nose cone dilator **28**. In this configuration, the user is free to manipulate the guide wire **26** and/or the secondary catheter **74** to make any necessary exchanges, such as, for example, to cannulate one or more of the branch vessels (such as the left subclavian artery, left carotid and/or innominate artery) extending from the main vessel **1** as described generally below.

In one non-limiting example of use, the introducer **18** may be tracked over guide wire **26** to a desired stent graft position within a vessel **1** as shown in FIG. **1**. The sheath **22** can then be distally retracted to expose the stent graft **34** (or stent graft **78** of FIGS. **4** and **6**) and any trigger wires or diameter reducing ties removed (such as wires **442**, **444** described below in connection with FIGS. **15-25**) to allow the stent graft to release from the introducer **18** and deploy within the vessel **1**. At this time, it may be desirable to cannulate a branch vessel, such as the left subclavian artery **14**, left carotid artery **12** and/or innominate artery **10**, extending from the main vessel **1**. To do so, the user may distally retract the guide wire **26** and secondary catheter **74**. This retraction will free guide wire **26** and secondary catheter **74** from the curved channel **68** in the nose cone dilator **28** as shown in FIGS. **5** and **6**. When the proximal end **76** of secondary catheter **74** is freed from the channel **68**, the guide wire **26** may then be manipulated by the user to cannulate a desired branch vessel. For example, the user may advance the guide wire **26** proximally and extend it into, and thereby cannulate the left subclavian artery **14**. If necessary or desired, a secondary stent graft, such as an extension stent graft (not shown) loaded on to a secondary introducer (not shown) may be tracked over the guide wire **26** and into the cannulated branch vessel to deliver and deploy the extension branch therein, thus restoring and/or maintaining patency to the branch vessel.

FIG. **6** shows another example of an introducer **18** with a stent graft **78** deployed from the proximal end of the introducer **18**. The guide wire **26** and secondary catheter **74** have been retracted distally out of the channel **68** in the nose cone dilator **28**. In one non-limiting example shown in FIG. **6**, the nose cone dilator **28** may have a straight lumen **64** extending between the proximal end **60** and distal end **58**, configured to receive a secondary guide wire **82** there through. If desired, the secondary guide wire **82** can be advanced through the straight lumen **64** and be extended out of the proximal end **60** of the nose cone dilator **28**. In doing so, the nose cone dilator **28** will still have a guide wire **82** extending there through to reinforce and constrain the positioning of the nose cone dilator **28** within the vessel lumen, while also maintaining a pathway for the introducer to be tracked over, even after guide wire **26** and/or secondary catheter **74** has been partially or fully withdrawn from the body.

FIG. **7** shows an enlarged view of the nose cone dilator **128** with a channel or lumen **168** extending there through. As previously described, the nose cone dilator **128** has channel **168** that extends from the proximal end **160** of the nose cone dilator **128** and terminates at aperture **170** formed in a sidewall **162** of the nose cone dilator. Curved channel **168** can be configured to receive a guide wire **126** and a secondary catheter **174** therein. As shown in FIG. **7**, the channel **168** may have a substantially constant inner diameter along its length, and near the proximal end **160** of the nose cone dilator **128**, the inner diameter of the channel **168** becomes narrowed at location **169**. In this way, the secondary catheter **174** can advance proximally through the channel **168** to the proximal end **160** of the nose cone dilator **128** but it cannot advance through the narrowed inner diameter portion **169** of the channel **168**. While the guide wire **126** may pass through the narrowed diameter portion **169** of the channel **168**, the secondary catheter cannot pass through this narrowed diameter portion **169** of the channel **168** and is therefore prevented from extending proximally out of the proximal tip **130** of the nose cone dilator **128**.

FIG. **8** shows another example of a conventional introducer assembly **200**. Introducer assembly **200** has a dilator tip **202** at its proximal end **210** and an external manipulation section or handle at the distal end **100**. A flexible delivery catheter **216** extends from a location distal to the handle **100** to the dilator tip **202**. Although this introducer **200** can be used in any area of the vasculature, it is described here as being used in the aortic arch.

As FIG. **8** and FIG. **9** show, an implantable prosthesis, such as a stent graft **224**, is carried on the delivery catheter

216 at the proximal end. A retractable introducer sheath 206 retains the stent graft 224 in a radially inwardly contracted delivery configuration on the delivery catheter 216 and can be retracted during deployment. The introducer 200 typically includes a pusher member 208 coaxial with at least a portion of the delivery catheter 216. The pusher member 208 extends proximally from the distal end or handle portion of the introducer and terminates at a location distal to the stent graft 224. In one example, the introducer assembly 200 includes a guide wire 220 which passes through the delivery catheter 216 and the dilator tip 202. In use, the introducer 200 can be tracked over the guide wire 220 to a desired location within the vasculature during the delivery and deployment procedure.

The delivery catheter 216 may extend proximally through the lumen 218 of the stent graft 224 to the dilator tip 202. In another example, where a fenestrated stent graft is used (such as the fenestrated stent graft 44 shown in FIG. 4), the delivery catheter 216 may extend into the distal end of the stent graft, then outwardly through the fenestration 80 formed in the sidewall of the graft and continue proximally to the dilator tip 202. In yet another example, where a branched stent graft is used (as shown in FIG. 9), the delivery catheter 216 may extend proximally into the distal end 228 of the stent graft 224, through the lumen of the internal graft branch 232 and continue out of the branch to the dilator tip 202.

The dilator tip 202 is preferably tapered and smooth, thereby facilitating atraumatic tracking and guiding of the introducer 200 through tortuous vasculature to a desired location within a vessel. In one example, the dilator tip 202 has a variable diameter. For example, the dilator tip 202 may be radially outwardly expanded, either partially or fully, during delivery of the stent graft 224. More specifically, when dilation is required, such as during insertion of the introducer 200 into a patient, the tip may be partially expanded, or alternatively, fully expanded, so that the outer diameter of the dilator tip 202 is at its maximum size. The introducer 200 may then be tracked to its desired position within the vessel. After graft deployment, the dilator tip 202 may be reduced in diameter to a smaller, radially inwardly contracted configuration. With the outer diameter of the dilator tip 202 reduced, the tip 202 can be retracted distally through the stent graft 224 for removal from the vessel.

In another example, where the delivery catheter 216 extends through a fenestration and/or side branch of the stent graft (such as, for example, the fenestration 80 formed in the sidewall of the graft body 44 of FIG. 4 and/or the branch 232 of the stent graft body 230 shown in FIG. 9), the reduction of the diameter of the dilator tip 202 advantageously facilitates retraction and withdrawal of the tip 202 through the lumen 218 of the stent graft body 230 and through the fenestration and/or through the graft side branch 232, while reducing the risk of the tip 202 snagging on any portion of the stent graft (including the fenestration and/or the graft side branch 232) or from snagging on any other portion of the introducer 200 during retraction of the dilator tip 202 out of the body. If desired, the guide wire 220 may be left in place within the main vessel 1, such as for further manipulation by the user to cannulate one or more branch vessels 10, 12 and/or 14, and then retracted at a later time during a procedure

FIG. 9 shows an introducer 200 with a deployed branched stent graft 224 and a variable diameter dilator tip 202 in a radially outwardly expanded-diameter configuration. FIG. 10 shows the introducer 200 of FIG. 9 with a deployed branched stent graft 224 and a variable diameter dilator tip 202 in a radially inwardly contracted or reduced-diameter configuration. The dilator tip 202 shown in FIGS. 9 and 10 may be a balloon-like resilient element constructed of a material having radially expandable and contractible properties. For example, the dilator tip 202 may be formed of polyurethane, nylon, PEBAX® (polyether block amide), PVC, plastics, rubbers and/or other resilient materials or a combination thereof. The tip 202 may have a substantially conical shape, spherical shape or onion shape to facilitate atraumatic insertion in a body lumen. The diameter of the outer surface of the dilator tip 202 may vary along its longitudinal length. For example, the tip 202 may have a proximal taper and/or a distal taper, with the center portion of the tip 202 having a greater diameter than the proximal and distal tapered portions when the tip 202 is in both the expanded condition and the contracted condition. A lumen extends through the dilator tip 202 between its proximal end 212 and distal end 214. The guide wire 220 extends proximally through the lumen of the delivery catheter 216 and can be extended through the lumen of the dilator tip 202.

FIG. 9 illustrates the proximal end of an introducer 200 with a branched stent graft 224 in a radially outwardly deployed configuration. The stent graft 224 may have a proximal end 226, distal end 228 and a tubular graft body 230 extending there between. One or more stents 234 may be attached to the tubular graft body 230. Branched stent graft 224 may have a proximal branch opening or aperture 236 located near the proximal end 226 of the stent graft 224. An internal graft branch 232 extends distally from the branch opening 236 within the lumen 218 of the stent graft 224. The dilator tip 202 and delivery catheter 216 may extend through the lumen 218 of branched stent graft 224. In one example shown in FIG. 9, the delivery catheter 216 and dilator tip 202 extend proximally through the lumen 218 of the stent graft 224, into the distal opening 238 of the branched stent graft 224 and exits the graft 224 through the proximal branch opening 236. Although not shown, in another example, a fenestrated stent graft can be used instead of a branched stent graft, and the delivery catheter 216 would pass out of the fenestration instead of through the branch opening.

As mentioned above, the dilator tip 202 is moveable between a radially outwardly expanded-diameter configuration (FIG. 9) and a radially inwardly reduced-diameter configuration (FIG. 10). During insertion of the introducer 200 into a patient, dilator tip 202 can be in an at least partially expanded configuration. Once a user has tracked the introducer 200 into a desired location and deployed the stent graft 224, the outer diameter of the dilator tip 202 may be reduced to a smaller diameter contracted configuration. The dilator tip 202 and delivery catheter 216 may then be withdrawn from the patient by pulling distally on the cannula, such as by retracting handle 100 as FIG. 10 illustrates.

Several different mechanisms can be used to control the variable diameter of the dilator tip 202. In one example, the dilator tip 202 has an inner cavity which can be filled with fluid, gel and/or gas as shown and described in U.S. Publication Application No. 2012/0109056, which is incorporated by reference herein. Another mechanism to control the diameter of the dilator tip 202 is by mechanical means. In one example, a flexible outer surface 240 covers an expandable structure such as, for example, a series of members, fingers, cages, mesh and the like which can be mechanically expanded and contracted. As the structure is expanded and contracted, the flexible outer surface 240 radially expands and contracts along with it, thus providing the user with control over the diameter of the dilator tip 202.

FIG. **11** shows one example of a mechanically expandable variable diameter dilator tip **202** in a reduced-diameter configuration. FIG. **12** shows the variable diameter dilator tip **202** of FIG. **11** in an expanded-diameter configuration. For the sake of clarity, a flexible outer **240** surface has been omitted from FIGS. **11** and **12** so that the internal structure can be observed and described.

As shown in FIGS. **11** and **12**, the delivery catheter **216** extends distally from the distal end **214** of the dilator tip **202**. At least one biasing member **242** is disposed within the center of dilator tip **202** and can extend longitudinally from the proximal end **212** to the distal end **214** of the dilator tip **202**. In one example, the biasing member **242** is a coil spring. One or more collars **244** may extend circumferentially around and crimp down the proximal and distal ends **212**, **214** of the dilator tip **202** and a hub **246** may be secured to the collar **244**.

Extending around the biasing member **242** between the proximal and distal ends **212**, **214** of the tip **202** is an expandable and contractible structure **248**. The structure **248** may be comprised of one or more fingers, wires, coils, fabrics, fibers, flexible arcuate members, cages, screens, disks, walls and the like, and may be constructed or formed from a single material or, alternatively, may be formed from a variety or combination of materials. In one example, at least a portion of structure **248** may be formed of any suitable material that may be expanded, such as by mechanical expansion. In other examples, at least a portion of the structure **248** may be formed from any suitable material that will result in self-expansion, such as shape memory material. As shown in FIGS. **11** and **12**, the structure **248** is a mesh. A flexible outer surface or member **240** (shown in FIGS. **9** and **10** but removed from FIGS. **11**, **11**A and **12**) may cover the mesh structure **248**.

Dilating tip **202** can be mechanically expanded and contracted such that the outer diameter of the dilating tip **202** can increase and decrease. Such radial outward expansion of the tip **202** may be achieved in several ways. First, in one example, one or more resilient inner central elongate member(s) **242** extends between the proximal and distal hubs **246** as shown in FIGS. **11** and **12**. The central elongate member **242** may include a coiled member or spring that extends substantially along the longitudinal axis. A proximal end of the elongate member **248** may be secured to the proximal hub **246** and a distal end of the elongate member may be secured to the distal hub **246**.

The mesh structure **248** extends radially outwardly at a location that is generally centered between the respective hubs **246** to form a substantially conical, elliptical, ovoidal or egg-shape. The elongate member **248** may be biased in either an expanded condition or a contracted condition, thereby biasing the tip **202** in either a diameter-reduced condition or a diameter-expanded configuration, respectively. The elongate member **248** is also preferably longitudinally extensible such that it can be lengthened or stretched to facilitate a radially constricted reduced-diameter configuration as shown in FIG. **11**. When the respective hubs **246** are extended away from each other in substantially opposing directions, the central elongate member **242** is extended. As a result, the dilator tip **202** becomes radially inwardly contracted. When the respective hubs **246** are moved towards each other, the central elongate member shortens. As a result, the dilator tip **202** becomes radially outwardly expanded as shown in FIG. **12**.

In another example, as shown generally in FIG. **11**A, radial outward expansion of the dilator tip **202** may be achieved by providing two separate inner central elongate members, namely proximal elongate member **242***a* and distal elongate member **242***b* coupled to each of the respective hubs **246**. The two central elongate members **242***a* and **242***b* may be in the form of springs or coils, or alternatively, two correspondingly shaped threaded members, one of which is configured to receive the other in a threadedly engaging manner. The two elongate members **242***a* and **242***b* preferably extend from each of the respective hubs **246** towards each other to a point where their respective terminating ends are adjacent and/or abut, and are capable of otherwise engaging each other. One of the elongate members **242***b* extending from the distal hub **246** may be rotated relative to the other elongate member **242***a*. Such rotation may be achieved by rotation of the delivery catheter **216** by the user, which, in turn, causes rotation of the distal elongate member **242***b*. Rotation of the distal elongate member **242***b* causes the two elongate members to engage each other (such as by one elongate member threadedly engaging the other elongate member) which, in turn, pulls the respective hubs **246** towards each other along the longitudinal axis. As the hubs **246** are pulled towards each other, the woven mesh **248** becomes extended radially outwardly at a location generally between the respective hubs **246** to form a radially outwardly expanded-diameter dilator tip **202** as illustrated in FIG. **12**. Similarly, rotation of distal elongate member **242***b* (such as by rotation of the delivery catheter **216** in the opposite direction) causes the elongate members **242***a* and **242***b* to unthread or otherwise disengage, thus moving the respective hubs **246** longitudinally away from each other, such that dilator tip **202** may be returned to a radially-inwardly reduced-diameter configuration, as illustrated in FIGS. **11** and **11**A. Expansion and contraction of the variable diameter tip **202** is further described in U.S. application Ser. No. 14/293,536, which is incorporated by reference herein.

In yet another example, FIG. **13** illustrates an introducer **300** that can be tracked into place within a vessel for delivery and deployment of a branched and/or fenestrated stent graft. The stent graft may be tracked into place and also pre-cannulated by the use of only a single wire. This may be achieved by utilizing an adaptation of a "cartridge" technique. This technique may be performed using a peel-away introducer sheath. FIG. **13** shows an example of an introducer **300** with a peel-away introducer sheath **304** for delivering and deploying a stent graft **310** using an adapted cartridge technique.

A guide wire **306** can first be inserted percutaneously into a patient's vasculature via a needle by known techniques. A delivery sheath **316**, coaxial with a dilator of sufficient size **303**, can be tracked over the guide wire **306** to the desired location in the vessel. The dilator **303** may have a nose cone **308** at its proximal end to provide an atraumatic tip for navigating the dilator **303** to a desired location within a vessel. The dilator **303** with the nose cone **308** at its proximal end can then be removed from the vasculature, leaving the sheath **316** in place. Sheath **316** can then serve as a conduit through which introducer **300** can be inserted.

A stent graft **310**, loaded on the proximal end of a delivery catheter **302** and constrained under a peel-away sheath **304**, can then be inserted in and through a hemostatic valve (not shown) near the distal end (not shown) of the delivery sheath **316** and pushed forward or proximally through the delivery sheath (such as by a pusher catheter **305**) to the intended deployment location within a patient's vasculature. Once there, a user can push the stent graft proximally and out of the proximal end of the peel away sheath **304** using pusher **305**, or alternatively, the user may remove the peel-away sheath **304** (distally) from the stent graft **310** by using the

ends **312** of the peel-away sheath **304** as handles and pulling them distally so that the peel-away sheath **304** separates longitudinally and splits at the distal end **314**. Next, a user can then distally pull (withdraw) the pull-away sheath **304** allowing the stent graft **310** to radially outwardly expand and deploy within the vessel.

Thus, when the stent graft **310** (loaded on the delivery catheter **302** within the peel-away sheath **304**) is inserted through the delivery sheath **316** that has already been tracked into place within the vessel, a second guide wire and dilator tip may be eliminated. In other words, the delivery sheath **316** provides a conduit through which the delivery catheter **302** may be inserted, thus, the need for another wire and/or dilating tip may be unnecessary. Alternatively, the introducer **300** may comprise a stent graft **310** (such as a branched stent graft **34** or a fenestrated stent graft **78** as described above) that is pre-loaded with a wire **318** so that once the stent graft **310** has been tracked to the desired location within a vessel and removed from the peel away sheath **304**, the wire **318** may be manipulated by the user to cannulate one or more branch vessels extending from the main vessel **1**.

In one example, the introducer assembly **300** is used in the aortic arch. The stent graft may be a singular tube, a fenestrated stent graft or a branched or bifurcated stent graft. The wire **318** can be passed through a branch or fenestration of the stent graft **310** as generally described above. Once the stent graft **310** is deployed, the guide wire **318** will be in place to perform any necessary cannulation of a branch vessel extending from the main vessel. In this way, the introducer **300** can be tracked into place within delivery sheath **316** and the stent graft branch and/or fenestration may also be pre-cannulated by the use of only a single wire.

In yet another example, FIG. **15** illustrates the proximal end of a delivery device or introducer assembly that can be tracked into place within a vessel to deliver and deploy a pre-cannulated branched and/or fenestrated stent graft. The wire used to track the device into place may be the same wire that is used to pre-cannulate the stent graft as well as the wire used to cannulate a branch vessel extending from the main vessel, as will be described in further detail below. The delivery device or introducer assembly may, in one example, be like that shown in FIG. **8**, for delivering a prosthesis such as stent graft **34**, **78** and/or **224** described above, or may be any other suitable introducer assembly chosen by one of skill in the art for use in a procedure.

The introducer may be pre-loaded with a guide wire that may be used to track the introducer into place within a vessel, with the same guide wire also pre-cannulating a side branch and/or fenestration formed in the stent graft. In other words, introduction of the introducer and cannulation of the internal graft branch or fenestration may be combined through the use of a single guide wire, and this same guide wire may then be further manipulated during use to cannulate one or more branch vessels extending from the main vessel **1**, including but not limited to the innominate artery **10**, the left carotid artery **12** and/or the left subclavian artery **14**.

FIG. **15** shows an example of an introducer assembly **400** for delivering and deploying a stent graft **404**. In FIG. **15**, an introducer sheath **402** has been partially retracted, allowing the proximal end of the stent graft **404** to be exposed. The proximal end **438** of the stent graft **404** is releasably coupled to the introducer, and in FIG. **15**, the proximal end **438** of the stent graft is retained in a radially inwardly contracted delivery configuration by one or more proximal fixation mechanisms or diameter reducing ties as will be described in further detail below. The distal end of the stent graft **404** may also be coupled to the introducer, and if desired, the stent graft **404** may be coupled to the introducer at one or more additional points along the main body of the stent graft between the proximal and distal ends.

Delivery of the stent graft **404** to the targeted location within a vessel can be accomplished using a single guide wire. A guide wire **406** can first be inserted percutaneously into a patient's vasculature via a needle by known techniques. Next, the introducer assembly **400** can inserted into the patient's vasculature and tracked over the guide wire **406**. Alternatively, the introducer assembly **400** can be inserted over the guide wire simultaneously with the guide wire **406** being tracked into place within a vessel.

An introducer sheath **402**, coaxial with a stent graft **404** coupled to the proximal end of a delivery catheter **412** (and constrained under sheath **402**) can be tracked over the guide wire **406** (through delivery catheter **412**) to the intended deployment location within a patient's vasculature. The introducer sheath **402** may extend proximally over the stent graft **404** to the distal end **440** of a nose cone dilator **408**. The nose cone dilator **408** may have a tapered atraumatic proximal tip for navigating to a desired location within a vessel. Once there, a user can then distally retract the sheath **402**, thus allowing the stent graft **404** to radially outwardly expand and at least partially deploy within the vessel. After sheath retraction, the proximal end of the stent graft **404** may still be releasably coupled to the delivery catheter **412** by the tri-fold proximal fixation mechanism **446** (as well as one or more additional points between the proximal end and distal end of the stent graft may also still be releasably coupled to the delivery catheter **412**) as described below.

The stent graft **404** may comprise a branched stent graft **34** or a fenestrated stent graft **78** as described above, or may be any other stent graft configuration as necessary or desired depending on the particular vessel(s) being treated and the procedure being performed. For exemplary purposes, the stent graft **404** as described further below is identified as a branched stent graft having an internal side branch **414**, but it would be recognized that the stent graft **404** may be any of the above-mentioned configurations or combinations thereof. The stent graft **404** may be pre-loaded with the guide wire **406**, so that once the stent graft **404** has been tracked to the desired location within a vessel, the guide wire **406** may be manipulated by the user to cannulate one or more branch vessels extending from the main vessel. In one example, the introducer assembly **400** may be used to deliver a stent graft into the aortic arch and the branch vessel extending from this main vessel **1** may be the left subclavian artery **14**, for example. The guide wire **406** can be passed through the lumen of a side branch (such as internal branch **414**) and/or fenestration (such as aperture **424**) of the stent graft **404** as generally described above. Once the stent graft **404** is deployed, the guide wire **406** will be in place to perform any necessary exchanges including cannulation of a branch vessel extending from the aortic arch. In this way, the guide wire **406** advantageously serves as a means to track the introducer assembly **400** to a desired location within the vessel **1** while also pre-cannulating the internal branch **414** or aperture **424** of the stent graft **404** with a single guide wire **406**. In other words, introduction of the introducer assembly and cannulation of the internal graft branch (or fenestration) may be combined through the use of a single guide wire **406**, and this same guide wire may then be further manipulated during use to cannulate one or more branch vessels extending from the main vessel.

As partially shown in FIG. **15**, stent graft **404** has been partially deployed because introducer sheath **402** once constraining it has been partially withdrawn, allowing the proximal end **438** of stent graft **404** to be unconstrained from the sheath **402**. In this example, stent graft **404** is a branched stent graft having a series of self-expanding stents **416** extending along the length of the graft body **426**. In this example, the branch **414** is an internal branch. In other words, the body **420** of the branch **414** extends within the lumen **422** of the stent graft **404**. The branch **414** has a proximal end **418** with a proximal opening **432** that extends from an aperture **424** formed in the sidewall of the graft body **426** and has a distal open end **428** that opens into lumen **422** of the stent graft **404**.

As shown in FIGS. **15** and **25**, the stent graft **404** carried by the introducer assembly **400** can be pre-loaded with the guide wire **406**. In one example, the guide wire **406** can extend proximally through the lumen **422** of the stent graft **404**, into the distal end **428** of the internal branch **414** and exit out of the branch **414** at the proximal branch opening **432**. The proximal tip **434** of the guide wire **406** can extend through a channel or lumen (not shown) in the dilator **408**. As shown in FIG. **25**, the proximal tip **434** of the guide wire **406** can, in use, be proximally advanced all the way out of the proximal end **436** of the dilator **408**.

FIGS. **17** and **24** illustrate the introducer assembly **400** of FIG. **15** when the introducer sheath **402** has been fully retracted by a user, but the stent graft **404** is not yet fully deployed because the proximal end **438** of stent graft **404** is still releasably attached or coupled to the delivery catheter **412** by one or more proximal attachment mechanisms and/or diameter reducing ties. In one example, as illustrated in FIG. **16**, the proximal end **438** of stent graft **404** is releasably coupled or tied to the delivery catheter **412** at the distal end **440** of the dilator **408** and/or at the proximal end **452** of the delivery catheter **412**. In one example, the proximal end **438** of stent graft **404** is tied to the delivery catheter **412** using at least two wires (first wire **442** and second wire **444**) to create a proximal tri-fold **446** in the graft body **426**. In addition to the proximal attachment, the stent graft **404** may also be releasably coupled or tied to the delivery catheter **412** at one or more additional points along the graft body **426** of the stent graft **404** between the proximal end **438** and distal end.

The delivery catheter **412** may be stiff enough to allow it to be pushed within a vessel lumen without collapsing, yet resilient or otherwise flexible enough to navigate the tortious vasculature. The delivery catheter **412** may be substantially straight or it may have a curve imparted to at least a portion of it. For example, as shown in FIGS. **15**, **16**, **24** and **25**, the proximal end **452** of the delivery catheter **412** may be bendable to conform to the curve of the aorta as it is tracked into place. Alternatively, the proximal end **452** of the delivery catheter **412** may be pre-curved so that it automatically conforms to the curve of the aortic arch **6** during delivery and deployment. As will be described in further detail below, and as shown in FIGS. **16**, **24** and **25**, the delivery catheter **412** extends through at least a portion of the stent graft lumen **422** and exits the lumen **422** through the proximal branch opening **432**. The proximal end **452** of the delivery catheter **412** then extends through aperture **424** and runs along the outside or external surface of the graft body **456** adjacent a first point **466** at the proximal end of the stent graft **404** as shown generally in FIGS. **16** and **19**.

With the delivery catheter **412** having a curve imparted to at least a proximal end or portion of it, the delivery catheter thereby tends to sit adjacent to or on the greater curve of the aorta as shown in FIGS. **24** and **25**. In other words, the proximal end **452** of the delivery catheter that runs along the outside surface of the graft body **456** and adjacent to a first point **466** at the proximal end of the stent graft **404** may be sandwiched between the outer surface of the graft body and the inner surface of the vessel wall within the aorta when then stent graft **404** is unsheathed during delivery and deployment, as shown in connection with FIG. **25**. With the stent graft **404** properly aligned with any one or more of the desired branch vessel(s), and with the stent graft **404** releasably attached to the delivery catheter at the proximal end **438** (and/or attached at any one or more points along the graft body **426** between the proximal and distal ends of the stent graft **404**), the stent graft **404** will preferably open away from the delivery catheter **412** (i.e., the stent graft **404** will expand downwardly and away from the delivery catheter **412**). Because the delivery catheter **412** extends along the greater curve of the vessel, the delivery catheter **412** serves as a "spine" for the stent graft **404**, to thereby maintain the position of the stent graft **404** (and the position of the internal branch **414**, the aperture **424** and/or proximal branch opening **432**) and properly align the stent graft **404** with the greater curve of the vessel as it is unsheathed during deployment, further guaranteeing proper orientation of the stent graft **404** within the vessel. Advantageously, with the delivery catheter **412** serving as a "spine" that is releasably attached to at least the proximal end **438** (and which may also be releasably attached to one or more additional points along the graft body **426**) maintains or assures rotational alignment of the stent graft **404**, ultimately facilitating alignment with and/or cannulation of the one or more branch vessels extending from the main vessel **1**, including but not limited to the left subclavian artery **14**. Full deployment of the stent graft **404**, including release of the one or more proximal attachment mechanisms or wires is described in further detail below.

FIGS. **17-21** illustrate a series of method steps in which at least two wires may be manipulated to tie and releasably couple the proximal end **438** of graft body **426** into the tri-fold configuration **446** shown in FIG. **16**. As seen in FIG. **17**, first wire **442** has a proximal end **448** and second wire **444** has a proximal end **450**. The first wire **442** and second wire **444** may be disposed within the lumen of the delivery catheter **412** and may extend proximally from the distal end (not shown) of the delivery catheter **412** and exit the proximal end **452** of delivery catheter **412** through one or more holes or apertures **454** formed in the delivery catheter **412**.

In one example, first wire **442** and second wire **444** exit the proximal end **452** of delivery catheter **412** just distal to the distal end **440** of dilator **408**. The proximal end **448** of first wire **442** and the proximal end **450** of second wire **444** may be threaded from the apertures **454** at a location outside of graft body **456**, threaded through graft body **426** at the proximal end **438** of the stent graft **404** and into the lumen **422** of the stent graft, as shown in FIG. **17**. Next, as seen in FIG. **18**, first wire **442** may be threaded from the inside of graft body **458** through the graft body **426** at a second location or point **462** to outside of the graft body **456**. In one example, first wire **442** may be threaded through the graft body **426** at a second location or point **462** that is approximately one-third of the circumference around the proximal end **438** of stent graft **404** from the first point **466**. Next, first wire **442** may be threaded back into the lumen **422** inside of the graft body **458** at or near the second point **462**. Similarly, the second wire **444** may be threaded from the inside of graft body **458** through the graft body **426** to the outside of the

graft body **456**. In one example, second wire **444** may be threaded at a third point or location **464** approximately two-thirds of the circumference around the proximal end **438** of stent graft **404** (or, in other words, the third point **464** is circumferentially spaced from the first point **466** in one direction and from the second point **462** in the opposite direction. Next, second wire **444** may then be threaded back into the graft body near the third point **464** to the inside of graft body **458** as shown in FIG. **18**.

As seen in FIGS. **19** and **20**, the proximal ends **448**, **450** of the first wire **442** and second wire **444**, respectively, are now both located within the stent graft lumen **422** and may be pulled taut to draw the graft body **426** radially inwardly towards the delivery catheter **412** from the two locations or points **462**, **464** where the first wire **442** and second wire **444** were threaded through the graft body **426**. This creates multiple "lobes" or "folds" of fabric at the proximal end **438** of the stent graft **404**. As shown in FIG. **16**, at least three lobes or folds **460** are formed, including at least a first fold, a second fold and a third fold when the wires **442** and **444** are pulled taut. As also shown in FIG. **16**, the proximal end **452** of the delivery catheter **412** runs along the outside of the graft body **456** adjacent a first point **466** at the proximal end of the stent graft **404**, thus, when the first and second wires **442**, **444** are pulled taut, the second and third points **462**, **464** of the stent graft are pulled towards and against the delivery catheter **412**, while the delivery catheter **412** presses against a first point **466**, thus drawing the first, second and third points **466**, **462**, **464** respectively, inwardly towards each other to pinch the proximal end **438** of the stent graft **404** into the tri-fold configuration **446**.

In one example, the first wire **442** and the second wire **444** can extend longitudinally from the external handle portion of the introducer assembly **400** and then be woven through the stent graft to form the proximal attachment as described above. In one example, the first wire **442** and second wire **444** can be pulled taut by threading the proximal ends **448**, **450** of the respective wires back through the center of the graft lumen and/or of the delivery catheter to extend distally back to the user so that the user can pull distally on the proximal ends **448**, **450** of the respective wires to pull them taut. In other words, after the wires are woven through the graft fabric as shown in FIGS. **18-21**, they may be tightened or otherwise pulled taut from the handle portion of the introducer so that the graft is pulled radially inwardly to create the tri-fold, and retained in that configuration until release is desired.

In another example, with the first wire **442** and second wire **444** releasably coupled to the graft in a manner previously described (such as in the tri-fold configuration, for example), the proximal ends **448**, **450** of the respective first wire **442** and second wire **444** may extend proximally into the distal end of the nose cone dilator **410** and be retained or held in that position within the nose cone dilator **410** by various releasable attachment means including friction fit, adhesives and the like. The distal ends of the first and second wires **442**, **444** may extend distally to the handle portion of the introducer and be manipulated by the user to pull the respective wires taut, thus holding the proximal end of the stent graft **404** in a constrained configuration. Release of the respective first and second wires **442**, **444** to release the proximal end of the stent graft **404** may be accomplished by the user manipulating one or more release mechanisms or knobs on the handle **200** of the introducer during deployment.

FIGS. **21** and **22** illustrate how the lobes or folds **460** formed at the proximal end **438** of the graft body **426** may be folded or wrapped circumferentially around the delivery catheter **412** to reduce the diameter of the proximal tri-fold **446**. More specifically, once the first wire **442** and the second wire **444** have been pulled taut and the graft body **426** has been pulled radially inwardly towards the delivery catheter **412** at the first, second and third points **466**, **462**, **464**, respectively, the multiple lobes or folds **460** may be folded down and wrapped upon each other, in either a clock-wise or counter clock-wise direction in a fan-blade or pin-wheel-like configuration as shown in FIGS. **21** and **22**. The inner surface of one lobe **460** lies down upon the outer surface of the adjacent lobe **460** thereby wrapping the proximal end **438** of the stent graft radially inwardly around and against the delivery catheter **412**. In one example, the three folds include a first fold, a second fold, and a third fold, wherein the first fold at least partially overlies the second fold, the second fold at least partially overlies the third fold, and the third fold at least partially overlies the first fold. Further, in another example, the first fold and the second fold may at least partially directly overlie the delivery catheter and the third fold may at least partially indirectly overlie the delivery catheter.

In this arrangement, the sheath **402** can extend proximally over the stent graft **404** to the nose cone dilator **408**, so that the introducer assembly is in a reduced-diameter low profile delivery configuration.

One of skill in the art would recognize that a single wire may be used (rather than two wires **442**, **444**) to weave in and out of the graft fabric to create a tri-fold configuration **446**. Alternatively, one or more wires may be used to create a bi-fold or other diameter reducing fixation arrangement at the proximal end **438** of the stent graft **404** to allow the proximal end **438** to be releasably coupled to the delivery catheter, including but not limited to various wire weaving patterns and various attachment mechanisms for securing the wire to the stent graft **404** and to the delivery catheter **412**.

FIGS. **23-25** illustrate various steps in one exemplary method for introducing and deploying a stent graft within a vessel using the introducer assembly **400**. For example, as illustrated in FIG. **23**, the introducer assembly **400** is tracked over guide wire **406** (through the lumen of the delivery catheter **412** and through the channel or lumen extending through the nose cone dilator **408**) to a location within a vessel **1**, with the stent graft (not shown) still covered and held in a radially inwardly contracted delivery configuration by introducer sheath **402**. The sheath **402** may then be distally retracted as shown in FIG. **24**, allowing the stent graft **404** to at least partially deploy from the introducer assembly **400** and become partially expanded within the vessel **1** at the site of the aneurysm **16**.

As previously mentioned, the delivery catheter **412** may have a curve imparted to at least a proximal end or portion of it, and the delivery catheter thereby tends to sit adjacent to or on the greater curve of the aorta as shown in FIGS. **24** and **25**. As such, the stent graft **404** will preferably open away from the delivery catheter **412** (i.e., the stent graft **404** will expand downwardly and away from the delivery catheter) as it is unsheathed during deployment, further guaranteeing proper orientation within the vessel. The delivery catheter **412** may thus be sandwiched between the outer surface of the stent graft **404** at the proximal end of the stent graft and the inner surface of the vessel wall, while facilitating alignment of the stent graft **404** within the vessel **1** as well as alignment with one or more branch vessels extending from the main vessel **1**. As illustrated in FIG. **24**, the proximal end **438** of stent graft **404** is still coupled to the

delivery catheter **412** by wires **442**, **444**, which hold the proximal end **438** in the tri-fold configuration **446** after the sheath **402** has been distally retracted.

Next, as shown in FIG. **25**, while the introducer assembly **400** remains within the vessel **1**, and the first wire (not shown) and second wire (not shown) have been released so that the proximal end **438** of the stent graft **404** is no longer constrained radially inwardly to the delivery catheter **412** by the proximal tri-fold shown in FIG. **16**. Once the stent graft **404** has been fully released from the delivery catheter **412**, the user may distally retract the delivery catheter **412** (with the nose cone dilator **408** at the proximal end thereof) and withdraw it from the vessel. The guide wire **406** may remain in place within the vessel, such that it extends proximally through the lumen **422** of the stent graft **404**, into the distal open end **428** of the internal branch **414**, through the body **420** of the branch and out of the stent graft **404** through the proximal opening **432** at the proximal end **418** of the internal branch **414** to a location external of the graft body at the proximal end of the stent graft **404**. In this way, a portion of the guide wire **406** extending proximally from the aperture **424** formed in the sidewall of the graft body is sandwiched between the outside surface **456** of the graft body **426** and the inside surface of the vessel wall. The guide wire may be manipulated by the user to extend the guide wire **406** into a branch vessel, such as the left subclavian artery **14**, to cannulate this branch vessel with the guide wire **406**.

At this time, if necessary and desired, a second delivery system (not shown), which may include a second delivery sheath with a bridging stent (not shown) may be extended over the guide wire **406** and tracked into the branch vessel, such as the left subclavian artery **14**. The bridging stent may be deployed and the second delivery system removed from the vasculature. The deployed bridging stent (not shown) then extends from the proximal end **418** of the internal branch **414**, through the aperture **424** formed in the sidewall of the graft body **426** and into the branch vessel to restore patency to the vessel.

In an alternative embodiment, as illustrated in FIG. **26**, the introducer assembly **400** may be provided with a delivery catheter having a relatively smaller diameter nose cone dilator **500** at the proximal end thereof. The relatively smaller diameter nose cone dilator **500** may be sized and shaped so as to minimize the risk of the nose cone dilator **500** catching on any portion of the stent graft **404** as the delivery catheter and nose cone dilator **500** are distally retracted around the proximal end **438** of the stent graft **404** and through the lumen **422** of the stent graft **404** (and/or retracted through any aperture **424** or internal side branch **414**) during removal from the vasculature. A delivery sheath **502** having an inwardly tapered proximal end may be provided to mate with the nose cone dilator **500**. In one example, the relatively smaller diameter dilator **500** may be between about 8 Fr and about 16 Fr. The tapered delivery sheath **502** is tapered radially inwardly at the proximal end **504** to mate with the nose cone dilator, and is constructed of a deformable, expandable and/or elastic material, and/or a material that can be easily torn, and/or has folds in the material such that it can be contracted and expanded. As such, the tapered delivery sheath **502** can deform as it is distally retracted over the stent graft **404**, therefore accommodating the larger outer diameter of the various other components of the introducer assembly **400** as the sheath slides distally by the user during deployment. FIG. **26** shows one example of a relatively smaller diameter dilator **500** and a tapered delivery sheath **502**.

In an alternative example, the proximal end **438** of the stent graft **404** may comprise a slit, hole, opening or pocket (not shown) formed within the wall of the graft body **426** that is located in front of (proximal of) the branch proximal end **418** at a point approximately where the proximal attachment wires **442** and **444** extend through the graft (refer to FIG. **17**). The nose cone dilator **408** and delivery catheter may then extend from the outer surface of the graft body, through the slit, hole or pocket and back into the lumen **422** at the proximal end **438** of the graft. In other words, the proximal end **452** of the delivery catheter would extend out of the proximal branch opening **432** and extend proximally on and along a portion of the outside surface at the proximal end **438** of the graft. Then, instead of continuing along the outer surface of the proximal end **438** of the stent graft **404** as shown in FIGS. **15** and **16**, the nose cone dilator **410** and delivery catheter **412** would then extend back into the graft lumen **422** through this slit, opening or pocket.

While various embodiments of the invention have been described, the invention is not to be restricted except in light of the attached claims and their equivalents. Moreover, the advantages described herein are not necessarily the only advantages of the invention and it is not necessarily expected that every embodiment of the invention will achieve all of the advantages described.

We claim:

1. A prosthesis delivery device comprising:

a delivery catheter having a proximal end,

a tubular prosthesis releasably coupled to the proximal end of the delivery catheter, wherein the prosthesis has a proximal end, a distal end, a lumen extending between the proximal end and distal end, a sidewall of graft material, an inner graft surface, an outer graft surface, and a fenestration formed in the sidewall of the prosthesis,

wherein the delivery catheter extends proximally through at least a portion of the prosthesis lumen and through the fenestration to a location external of the prosthesis and abutting a first point on the outer graft surface of the graft at the proximal end,

a first proximal attachment mechanism releasably coupling a second point on the proximal end of the prosthesis to the delivery catheter, wherein the second point is circumferentially spaced from the first point;

a second proximal attachment mechanism releasably coupling a third point on the proximal end of the prosthesis to the delivery catheter, wherein the third point is circumferentially spaced from the first point in one direction and from the second point in the opposite direction;

wherein the delivery catheter further comprises at least one opening formed in a sidewall thereof and wherein the first proximal attachment mechanism extends from the at least one opening formed in the delivery catheter and is releasably coupled to the prosthesis, and wherein the second proximal attachment mechanism extends from the at least one opening formed in the delivery catheter and is releasably coupled to the prosthesis;

wherein the first and second proximal attachment mechanisms draw the second and third points to the first point to form three folds of graft fabric;

wherein the folds extend about the delivery catheter in a folded configuration such that at least a portion of the outer surface of the graft abuts the outer surface of the delivery catheter.

2. The prosthesis delivery device of claim **1**, wherein the three folds include a first fold, a second fold, and a third fold,

wherein the first fold at least partially overlies the second fold, the second fold at least partially overlies the third fold, and the third fold at least partially overlies the first fold.

3. The prosthesis delivery device of claim **1**, wherein the three folds include a first fold, a second fold, and a third fold, wherein the first fold at least partially directly overlies the delivery catheter, the second fold at least partially indirectly overlies the delivery catheter, and the third fold at least partially indirectly overlies the delivery catheter.

4. The prosthesis delivery device of claim **1**, wherein the three folds include a first fold, a second fold, and a third fold, wherein the first fold at least partially directly overlies the delivery catheter, the second fold at least partially indirectly overlies the delivery catheter, and the third fold at least partially overlies the first fold.

5. The prosthesis delivery device of claim **1**, wherein the folded configuration is a spiral configuration.

6. The prosthesis delivery device of claim **1** wherein the first and second attachment mechanisms each comprise a loop of wire, suture, filament or thread that extends at least partially through a lumen of the delivery catheter to a respective second or third point on the proximal end of the prosthesis.

7. The prosthesis delivery device of claim **6** wherein the delivery catheter comprises a first opening and a second opening formed in a sidewall thereof, and wherein the first attachment mechanism extends out of the lumen of the delivery catheter through the first opening and wherein the second attachment mechanism extends out of the lumen of the delivery catheter through the second opening.

8. The prosthesis delivery device of claim **1** wherein the second point is spaced in a first direction one-third about the circumference of the prosthesis from the fenestration, and wherein the third point is spaced in a second direction one-third about the circumference of the prosthesis from the fenestration.

9. The prosthesis delivery device of claim **1** wherein the three folds of graft fabric are circumferentially folded upon each other.

10. A prosthesis delivery device comprising:

a delivery catheter having a proximal end,

a tubular prosthesis releasably coupled to the proximal end of the delivery catheter, wherein the prosthesis has a proximal end, a distal end, a lumen extending between the proximal end and distal end, a sidewall of graft material, an inner graft surface, an outer graft surface, and a fenestration formed in the sidewall of the prosthesis,

wherein the delivery catheter extends proximally through at least a portion of the prosthesis lumen and through the fenestration to a location external of the prosthesis and abutting a first point on the outer graft surface at the proximal end of the prosthesis;

a first proximal attachment mechanism releasably coupling a second point on the proximal end of the prosthesis to the delivery catheter, wherein the second point is circumferentially spaced from the first point;

a second proximal attachment mechanism releasably coupling a third point on the proximal end of the prosthesis to the delivery catheter, wherein the third point is circumferentially spaced from the first point in one direction and circumferentially spaced from the second point in the opposite direction;

wherein the delivery catheter further comprises at least one opening formed in a sidewall thereof and wherein the first proximal attachment mechanism extends from the at least one opening formed in the delivery catheter and is releasably coupled to the prosthesis, and wherein the second proximal attachment mechanism extends from the at least one opening formed in the delivery catheter and is releasably coupled to the prosthesis;

wherein the first and second proximal attachment mechanisms draw the second and third points to the first point to form first, second, and third folds of graft fabric;

wherein at least a portion of the outer surface of at least one of the first, second and third folds abut the outer surface of the delivery catheter in a folded configuration.

11. The prosthesis delivery device of claim **10**, wherein the first fold at least partially overlies the second fold, the second fold at least partially overlies the third fold, and the third fold at least partially overlies the first fold.

12. The prosthesis delivery device of claim **10**, wherein the delivery catheter extends proximally from the fenestration formed in the sidewall of the prosthesis along an outer surface of the prosthesis sidewall.

13. The prosthesis delivery device of claim **10**, wherein the three folds include a first fold, a second fold, and a third fold, wherein the first fold at least partially directly overlies the delivery catheter, the second fold at least partially indirectly overlies the delivery catheter, and the third fold at least partially indirectly overlies the delivery catheter.

14. The prosthesis delivery device of claim **10**, wherein the three folds include a first fold, a second fold, and a third fold, wherein the first fold at least partially directly overlies the delivery catheter, the second fold at least partially indirectly overlies the delivery catheter, and the third fold at least partially overlies the first fold.

15. The prosthesis delivery device of claim **10**, wherein the folded configuration is a spiral configuration.

16. The prosthesis delivery device of claim **10** wherein at least a portion of the delivery catheter has a curve imparted to it.

17. The prosthesis delivery device of claim **16** wherein at least a portion of the prosthesis substantially conforms to the curve of the delivery catheter.

18. The prosthesis delivery device of claim **10** wherein the delivery catheter comprises at least one opening formed in a sidewall thereof, the at least one opening located closely adjacent the proximal end of the prosthesis; and wherein the first and second attachment mechanisms extends out of a lumen of the delivery catheter through the at least one opening.

19. The prosthesis delivery device of claim **10** wherein the delivery catheter comprises a first opening and a second opening formed in the sidewall thereof;

wherein the first attachment mechanism extends from the first opening formed in the delivery catheter, through the sidewall of the prosthesis and into the prosthesis lumen, then extends out of the prosthesis lumen through the second point at the proximal end of the prosthesis, then extends back through the prosthesis sidewall into the prosthesis lumen, and

wherein the second attachment mechanism extends from the second opening formed in the delivery catheter, through the sidewall of the prosthesis and into the prosthesis lumen, then extends out of the prosthesis lumen through the third point at the proximal end of the prosthesis, then extends back through the prosthesis sidewall into the prosthesis lumen.

20. A prosthesis delivery device comprising:

a delivery catheter having a proximal end,

a tubular prosthesis releasably coupled to the proximal end of the delivery catheter, wherein the prosthesis has

a proximal end, a distal end, and a lumen extending between the proximal end and distal end, and a fenestration formed in a sidewall of the prosthesis,

wherein the delivery catheter extends proximally though at least a portion of the prosthesis lumen and through the fenestration formed in the sidewall of the prosthesis such that the delivery catheter abuts a portion of an outer surface of the prosthesis,

a first attachment mechanism releasably coupling a second point at the proximal end of the prosthesis to the delivery catheter,

a second attachment mechanism releasably coupling a third point at the proximal end of the prosthesis to the delivery catheter,

wherein the delivery catheter further comprises at least one opening formed in a sidewall thereof and wherein the first proximal attachment mechanism extends from the at least one opening formed in the delivery catheter and is releasably coupled to the prosthesis, and wherein the second proximal attachment mechanism extends from the at least one opening formed in the delivery catheter and is releasably coupled to the prosthesis;

wherein the first and second proximal attachment mechanisms have a first configuration in which the proximal end of the prosthesis is coupled to the delivery catheter and a second configuration in which the proximal end of the prosthesis is released from the delivery catheter, and

wherein at least a portion of the outer surface of the prosthesis abuts an outer surface of the delivery catheter when the proximal end of the prosthesis is coupled to the delivery catheter.

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